WASHINGTON STATE

DEPT. OF HEALTH

REPORT ON COMMENTS CHAPTER 246-320 WAC

JULY, 2006

HOSPITAL LICENSING REGULATIONS

SECTIONS:

WAC 246-320-001 Through
WAC 246-320-99902

July 18, 2006

TO: Interested Parties and Stakeholders

FROM: Allen Spaulding, Rules Coordinator

SUBJECT: Hospital Licensing Rules, Chapter 246-320 WAC – Report on Comments

At the June 21, 2006 public meeting, participants completed a review of 107 comments on 49 rule proposals that were submitted during the public comment period. The meeting facilitator asked participants to indicate one of three levels of support in order to assess each comment on proposal. The meeting actions are captured and/or recorded in the Report on Comments (ROC) as follows:

1. **I support this comment as proposed** and suggest that DOH include it in the rule revision.
2. **I support this comment with** the following **modifications**, and I suggest that DOH include the modified proposal in the rule revision.
3. **I do not support this comment** in principle or with modification, and would like DOH to exclude it from the rule revision.

Additionally, there are three other meeting actions reported as follows:

1. **Commentary -** The comment did not propose a change and therefore is taken as advisory only.
2. **Withdrawn –** The comment was withdrawn by the original submitter.
3. **Tabled Discussion -** the participants' agreed this discussion will be deferred to a future public forum.

The purpose of the ROC and the rules development process is to capture and report the participants' recommendations, to the department, for changes to the existing chapter 246-320 WAC. The department has not endorsed the comments contained in the ROC.

Next Steps

CR-102 filing and Public Rules Hearing: The department will conduct an internal review and assess the recommendations from the first and second public meetings/reports for changes to the existing chapter 246-320 WAC. A notice accompanied by the proposed rule changes will be published and sent to all interested parties in advance of the hearing date. Anyone may attend the public rules hearing and present their views on the reports, public meeting actions, and final proposed rule changes.

For questions regarding this process, contact Allen Spaulding at (360) 236-2929, or e-mail to: al.spaulding@doh.wa.gov.

Thank you and feel free to contact me with any questions or concerns.

Sincerely,

Allen Spaulding
(360) 236-2929 or al.spaulding@doh.wa.gov
FAX (360) 236-2901

Proposals 001 & 002 – Comment 1 **Supported as Proposed**

Submitter: Washington State Psychological Association
Section: 246-320WAC
Recommendation: WSPA recommends further modification of the 4/19/2006 modified proposal 1(b): delete the term "psychological." WSPA suggests that modified proposal 1(b) read as follows: "Emotional Abuse" means verbal behavior, harassment, or other actions which may result in emotional or behavioral stress or injury.

WSPA further supports the language in modified proposal (95), removing the term "psychiatric condition" to be replaced with mental disorder.

In proposal 002, WSPA supports the modified proposal language to replace the term "psychiatric disturbance" with symptoms of mental disorder.

Substantiation: 1(b) Substantiation: The term "psychological" is a protected term under 18.83.020 RCW.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 001 - Comment 2 **Supported as Proposed**

Submitter: Sandy Dahl
Section: 246-320-010
Recommendation: Delete the proposed text for definition (95) as follows:

(95) "Restraint" means any method used to prevent or limit free body movement including, but not limited to, involuntary confinement, ~~an apparatus~~ a physical or mechanical device, or a drug given not required to treat a patient's medical symptoms. ~~A patient in restraint is continually monitored face-to-face by an assigned staff member or continually monitored by staff using both video and audio equipment~~.
Substantiation: The new wording requires that any patient in restraints be monitored face to face by an assigned staff member through the use of a staff member using bother video and audio continuous monitoring. This would require a significant increase in the number of staff required to meet this measure as well as additional equipment (audio and video monitoring). Patients on any unit potentially could be in restraints; this would cause significant cost to the organizations without any reimbursement for this additional expense in an environment where reimbursement is challenging anyway. This criteria is appropriate for a patient who is in seclusion but not for the general medical surgical patient that is in a physical restraint. There is not data to support that there have been bad outcomes due to lack of this monitoring. Organizations who opt to have JCAHO survey them are already meeting the restraint standard.

Level of Support: Supported as Proposed

Modified proposal as follows:
(95) "Restraint" means any method used to prevent or limit free body movement including, but not limited to, involuntary confinement, ~~an apparatus~~ a physical or mechanical device, or a drug given not required to treat a patient's medical symptoms.
(96) "behavioral restraint" means patient in restraint is continually monitored face-to-face by an assigned staff member or continually monitored by staff using both video and audio equipment.

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 001 - Comment 3 **Supported as Proposed**

Submitter: Gail T. McGaffick for WA Acupuncture & Oriental Medicine Association
Section: 246-320-010
Recommendation: Please remove definition of "practitioner" from the general definition section, and relocate it to the section that deals with mandatory reporting by hospitals.

Substantiation: The definition is potentially confusing, and potentially limiting in the general definition section because it only lists certain providers, to exclude licensed acupuncturists. This specific definition should only be used in the context of the legislation in which it is included (mandatory reporting), and should not be placed in a general definition section. To do so could imply that only those practitioners listed should be allowed to provide care in a hospital. We affirm our comments that decisions on which types of providers and which individual providers should be allowed to practice in hospitals should be the decision of the individual hospital.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 001 - Comment 4 **Supported as Proposed**

Submitter: Gail T. McGaffick for WA Acupuncture & Oriental Medicine Association
Section: 246-320-010
Recommendation: First choice. Please delete definition of "Licensed independent practitioner."

Second choice. Amend the language to read: "…having the authority to order medications ~~and~~ or order or provide other therapeutic interventions for patients."

Substantiation: The definition is potentially confusing, and potentially limiting because it requires practitioners to have the ability to both order medications and other therapeutic interventions. In addition, it does not cover the case of a practitioner who provides a therapeutic intervention, such as a licensed acupuncturist. We believe that decisions on which types of providers, and which individual providers are allowed to practice in hospitals, should be left to the decision of the hospital. This definition potentially limits a hospital's authority by excluding providers who provide an intervention, rather than order one.

Level of Support: "First Choice" Supported as Proposed

Modified proposal as follows:

Meeting discussion: The group supports striking the definition for Licensed independent practitioner.

Proposal 001 - Comment 5 **Supported with Modification**

Submitter: Byron Plan
Section: 246-320-010
Recommendation: Change the definition of "adverse event" to be consistent with the legislation passed (HB 2292).

> "Adverse health event" or "adverse event" means the list of serious reportable events adopted by the national quality forum in 2002, in it's consensus report on serious reportable events in health care. Such events are a negative consequence of care that results in an unintended injury, ~~or~~ illness, ~~which may or may not have been preventable. As used in this chapter, such an event results in~~ death or loss of bodily function lasting more than

seven days or is still present at the time of discharge. ~~Events listed in this chapter have been developed by the National Quality Foundation as "serious reportable events".~~

Not necessary to define "swing bed" as this is a designated use of a bed that meets the definition as written. This same comment applies to "long term bed" which is also covered in the definition of bed.
Remove/delete the definition of "licensed independent practitioner"
Move the definition of "practitioner" to section 145 (Leadership) where the requirement for reporting a practitioner to the DOH is written.

Change the definition of protocols and standing order – delete all the last two sentences of the definition.

Move the second sentence in the definition of "seclusion" to section 365
Seclusion means the involuntary confinement of a patient in a room or area where the patient is physically prevented from leaving. (A patient in seclusion is continually monitored face-to-face by an assigned staff member or continually monitored by staff using both video and audio equipment or technology.)

Create a definition for emergency room/department.
"Emergency department" means the area of a hospital responsible for the administration and provision of unscheduled medical or surgical care to patients in need of immediate attention where staff provide initial treatment to patients with a broad spectrum of illnesses and injuries, some of which may be life-threatening and requiring immediate attention**.**

"Emergency room" means a space in the emergency department set apart by floor-to-ceiling partitions on all sides with proper access to a corridor and with all openings provided with doors or windows.

Substantiation: Change the definition of "adverse event" to be consistent with the legislation passed (HB 2292). The original proposal was written before the law changed.

During the March meeting, questions were asked regarding the need to include "swing beds" and "long term care beds" in the proposed definition of beds. The definition of beds as written is inclusive of all types of care and does not need special modifiers or care designations.

The Department does not see a need to define "licensed independent practitioner". Hospitals define by policy and medical staff bylaw who can practice, the credential process and the authorities granted to each individual.

Based on discussion at the March meeting, the Department proposes moving the definition of "practitioner" to section 145 which is the portion of the rule in which the term is used as relates to the requirement for hospitals to report unprofessional conduct.

Change the definition of protocols and standing order – delete all the last two sentences of the definition. This is based on discussion at the March meeting. There is no need to be so prescriptive in rule. Hospitals establish by policy and procedure where and to whom a protocol and standing order applies.

Move the second sentence in the definition of "seclusion" to section 365. This is based on discussion at the March meeting. The second sentence is an operational standard, not part of a definition.

Create a definition for emergency room/department. Asked the Department to suggest language at March meeting.

Level of Support: Supported with Modifications

Modified proposal as follows: Revise text as follows:

"Emergency room" means a space in the emergency department set apart by floor-to-ceiling partitions on all sides with proper access to a ~~corridor~~ exit access and with all openings provided with doors or windows.

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 001 - Comment 6 **Supported as Proposed**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Disagree with # 95 "a patient in restraint is continually monitored face to face". This is more stringent that JCAHO regulations that require only patients in Behavioral restraint to be monitored face to face. This proposal does not distinguish between Medical, Behavioral and Law enforcement restraints as does JCAHO.

Disagree with #88 that a protocol requires an order from an LIP and must be recorded in the patient record. This prohibits hospital wide approved protocols from being implemented without a specific order (examples are a Weaning protocol in ICU and a pneumococcal and influenza vaccine protocol). These are frequently approved by the governing medical staff body and implemented without an individual LIP order. This tactic is used to help mandate all LIP comply with CMS initiatives and best practices.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: The Nursing commission wants consistency with JCAHO standards. This issue is addressed in proposal #1 - comment #2.

Proposal 002 - Comment 2 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-010
Recommendation: Definition for "severe pain"

"Severe pain" means a level of pain reported by a patient of 8 or higher based on a 10 point scale with 1 being the least pain and 10 being the most pain.

Substantiation: Response to request for Department to suggest a definition as the term "severe pain" found in the definition of "emergency medical condition.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: The question was asked why a scale of 1-10, and is this supported by some recognized standard for care. The following discussion purported that this is a commonly accepted practice and it was noted that other similar scales could be used when the number value is associated – such as colors or images.

Proposal 002 - Comment 3 **Commentary**

Submitter: Nursing Commission
Section: 246-320-010
Recommendation: Further defines emergency medical conditions. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 003 - Comment 1 **Supported as Proposed**

Submitter: Nancy Lyons & Susan Spohr
Section: 246-320-001
Recommendation: We agree with the new proposed wording adding electronically recorded. Delete the remainder of the new proposed wording.

Substantiation: The current definition is acceptable as written. Please do not limit the use of evidence-based protocols to emergency situations.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 003 - Comment 2 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Relates to the protocol issues discussed above, it is seeking clarification.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: See Comment #3, Proposal #3

Modified proposal as follows:

Meeting discussion: The Nursing Commission was seeking clarification. This comment did not propose a change and therefore is taken as advisory only.

Proposal 003 & 009 - Comment 3 **Supported with Modification**

Submitter: Gary Wickman
Section: 246-320-010
Recommendation: (88) "Protocols" and "standing order" mean written or electronically recorded descriptions of actions and interventions for the implementation by designated hospital personnel under defined circumstances and authenticated by a legally authorized person under hospital policy and procedure.

Implementation of a protocol requires an order from a licensed independent practitioner and when used must be recorded in the patient record. Certain orders imply that related protocols be activated when that order is initiated and signed by an LIP, for example but not limited to:

1. When an LIP writes an order to initiate Mechanical Ventilation, the Protocol for "Daily Spontaneous Breathing Trials" is also initiated.

All related protocols need to be clearly identified by policy or procedure and:

2. Approved by Medical Staff
3. Based on Clinical Practice Guidelines, where applicable
4. Be evidence based

A standing order or protocol is for an emergency situation, including but not limited to cardio-pulmonary resuscitation, Rapid Response Team call, or anaphylactic shock and does not require an order from a licensed independent practitioner prior to implementation.

Substantiation: We feel that the recommended changes more clearly identify how protocols can be activated or implemented whether they are related to other orders or are implemented due to emergency situations. The related protocols will all have a parent order signed by the LIP and will be referred to in policy or procedure approved by the Medical Staff and the authorized person under hospital policy or procedure. We also wanted to clearly identify Rapid Response Teams as a possible emergent call situation. Rapid Response Teams have been shown to reduce the number of cardio-pulmonary resuscitations by as much as 65%.

Reference:

- Bellomo R, Goldsmith D, Uchino S, et al. A prospective before-and-after trial of a medical emergency team. Medical Journal of Australia. 2003; 179(6): 283-287.

These Rapid Response Teams can rely on Protocols that have been defined by evidence based practice that has been shown to be effective and which have been approved by Medical Staff. The use of protocols leads to standardization of care which should be based on the best evidence out there and approved by medical staff. Protocols let the person at the bedside better match the care to the patient. Following protocols have led to better quality outcomes, decreased length of stay, and decreased health care costs.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

(88) "Protocols" and "standing order" mean written or electronically recorded descriptions of actions and interventions for the implementation by designated hospital personnel under defined circumstances ~~and authenticated by a legally authorized person~~ under hospital policy and procedure.

Implementation of a protocol or a standing order requires authentication. ~~an order from a licensed independent practitioner and when used must be recorded in the patient record. Certain orders imply that related protocols be activated when that order is initiated and signed by an LIP, for example but not limited to:~~

1. ~~When an LIP writes an order to initiate Mechanical Ventilation, the Protocol for "Daily Spontaneous Breathing Trials" is also initiated.~~

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 004 - Comment 1 **Not Supported**

Submitter: Nancy Lyons & Susan Spohr
Section: 246-320-010
Recommendation: Delete proposed new section in its entirety. The principle of adequate, safe and appropriate staffing is shared by administrators, managers and staff in health care organizations. It is addressed in existing statutes and regulations (e.g. 246-320-345).

Substantiation: The language proposed is too onerous and prescriptive to implement and manage. Facilities already governed by several regulatory agencies on this topic including DOH, JCAHO and via their collective bargaining agreements.

Level of Support: Not Supported

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 004 - Comment 2 **Commentary**

Submitter: Patricia Di Egidio-Tobis
Section: 246-320-010
Recommendation: Strongly support new language on safe nursing staffing as proposed. I've been and RN for over 33 yrs and continue to work full-time. Recently I've been at pt both in a hospital and nursing rehab center. Having proper staffing is essential based not only on pt census.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: Nursing Commission strongly supports the new language. This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 3 **Commentary**

Submitter: Kathleen Gilbertson-Stimpfle
Section: 246-320-010
Recommendation: Strongly support new language on safe nursing staffing as proposed.

Substantiation: I belong to the Employee Safety Committee at Sacred Heart Medical Center, Spokane, WA. I provide direct bedside care as an RN.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 4 **Commentary**

Submitter: Jean Erickson
Section: 246-320-010
Recommendation: Strongly support new language on safe nursing staffing as proposed with the following changes.

Safe RN staffing (Proposal #4)

- Require each hospital to develop and implement a staffing plan for nursing services based on criteria such as census, intensity of patients, skill mix or nursing personnel.
- Require the involvement of a staffing committee composed of at least ~~one half~~ (three fourths) registered nurse who provide direct patient care (with each unit represented)
- Allow for shift-to-shift adjustments in staffing levels based on the assessment of registered nurses providing direct patient care on ~~a unit~~ (the unit in question)
- Require the hospital to maintain daily records of patient census and the number (education, and certification) of nursing personnel per unit per shift.

Substantiation: The nurses must be in majority to insure that decisions are being made by persons with direct knowledge of the staffing issues. The staffing decisions must be made by the nurses involved, not nurses from other units not having direct knowledge of the unique workings and needs of the particular patients on a particular unit.

The current wording is too broad. Filling an RN need with and LPN or nurses aid is not adequate of acceptable. The public has a right to know the expertise of the person providing their care.

See research by Linda Aiken and related persons. See research by Johnson Wood Foundation, etc.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 5 **Commentary**

Submitter: Julie Weinberg
Section: 246-320-010
Recommendation: Strongly support new language on safe nursing staffing as proposed.

Substantiation: This new language would help support the ongoing efforts that many RNs have been trying to get mandated and be involved at a decision making level when it comes to staffing. I believe the staff nurses at the bedside, when it comes to developing staffing plans and models while meeting the needs of acutely ill patients; we have got to have the ability to design these staffing models, trial them and evaluate them and if needed change them on an as needed basis. The constant turnover and changing of the acuity of patients who we are taking care of in today's healthcare institutions can not be by a nurse to number model and cost basis only model.

This is based on my own experience and opinion.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 6 **Commentary**

Submitter: Cathy
Section: 246-320-010
Recommendation: Strongly support new language on safe nurse staffing as proposed.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 7 **Not Supported**

Submitter: Shayne Blevins
Section: 246-320-010
Recommendation: The nurse to patient ratio should follow the California's nurse to patient ration law which will be effective in 2008. There should be no more than 4 patients per nurse at all times, doesn't matter what shift.

Substantiation: Patient care is deteriorating, patient safety deteriorating, studies have shown that patient status deteriorates when nurse has more then 4 patients each. Adopt California Law AB394 R-37-01, Massachusetts HB 182.

Level of Support: Not Supported

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 004 - Comment 8 **Commentary**

Submitter: Rep. Dawn Morrell, RN
Section: 246-320-010
Recommendation: I strongly support the proposal as submitted and suggest that DOH include it in the rule revision.

Substantiation: These staffing plans will serve as a basis for allowing nurses to report chronic understaffing. This will hopefully prevent events similar to what recently occurred at Puget Sound Behavioral Health Hospital in Tacoma.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 9 **Not Supported**

Submitter: Sandy Dahl
Section: 246-320-010
Recommendation: I would strongly recommend that the entire section be deleted and the language amended to say the following: 1. each hospital have a staffing committee; membership can be as described in the proposal; 2. committee meets on a semiannual basis to educate staff about staffing and provide a forum for feedback about staffing concerns 3. Staffing concerns are problem solved by the group and others members (Nurse Executive) 4. Solutions are shared with the staff via meeting minutes, open forum. 5. That the hospital uses defined rational or criteria for staffing decisions 6. Each hospital develops/implements a staffing plan for nursing services and updates the plan annually; plan includes staffing matrix by unit with minimum number, with suggested skill mix. 7. The staffing plan on a shift basis is communicated to unit by Nursing Supervisor or designee. 8. DOH may review staffing plans, minutes of staffing meetings at regular surveys

Substantiation: The suggested content if taken in whole would require an acuity system be in place (information software tool) to collect some of the real time staffing data with a corresponding proactive action taken to staff the next shift; these systems are expensive (anywhere from $80,000 to $200, 000 depending on contract options), the available models do not contain all necessary components, it requires manpower to operationalize daily and maintain, including running/interpreting reports as well as extra time from a bedside RN to provide data; limits or defines hospital options to staff which may not be able to be actualized; potentially would require hospitals to close beds and limit care to their constituents and impact access and quality. The reporting requirements to the state are burdensome and drive hospital costs up without reimbursement for those costs; some of these measures were looked at by the legislature this past year and pulled off the table because of the negative impact on the healthcare industry; content suggested approaches mandated staffing ratios in a time when we can not put out enough graduates to meet the need; is prescriptive in its approach to this issue; staffing is done most effectively when taking into account the larger picture of needs across the entire organization; it is more appropriate that a person make staffing decisions who has organizational authority and can

allocate resources across than a staff nurse on a particular unit; certainly the staff nurse or charge nurse should give complete data to the person who has organizational authority to made staffing decisions so these decisions are sound.

Level of Support: Not Supported

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 004 - Comment 10 **Commentary**

Submitter: Joyce A Daniels
Section: 246-320-010
Recommendation: Strongly support new language on safe nurse staffing as proposed

Substantiation: I strongly support this proposal in order to give quality patient care.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 004 - Comment 11 **Tabled Discussion**

Submitter: Byron Plan
Section: 246-320-010
Recommendation: Revise the proposed definition. Change the concept from a committee to a plan and include all direct care staff.

(a) "Staffing plan ~~committee~~" means a document ~~committee~~ established by the hospital that defines a process individual units of the hospital will use to determine the number and type of direct care staff necessary to safely provide patient care. ~~with at least one-half of its members who are registered nurses currently providing direct patient care. If registered nurses are represented by a collective bargaining representative, the registered nurse representatives must be selected by the collective bargaining representative. Participation in the committee must be considered a part of the employee's regularly scheduled workweek.~~

~~(b) "Patient care unit" means any unit of the hospital that provides patient care.~~

~~(c) "Intensity" means the level of patient needs as determined by a registered nurse providing direct patient care taking into account at least the following factors:~~

~~(i) Severity and urgency of the patient's admitting condition;~~
~~(ii)Scheduled procedures;~~
~~(iii)Patient's ability to meet health care requisites;~~
~~(iv) Patient's availability of social supports;~~
~~(v) Age and functional ability of the patient;~~
~~(vi)Communications skills of the patient; and~~
~~(vii)Other needs identified by the patient and by the registered nurse.~~

~~(d) "Skill mix" means the number of registered nurses, licensed practical nurses, and unlicensed assistive personnel providing direct patient care~~.

Revise the proposed wording for the plan.

(2) A ~~Each~~ hospital must ~~in the state shall~~ develop and implement a~~s~~ staffing plan ~~for nursing services~~. The plan must be reviewed and updated annually and ~~filed with the department. The written staffing plan~~ must:

(a) ~~Set~~ Include a ~~the~~ minimum number of direct care staff ~~and skill mix of registered nurses, licensed practical nurses, and unlicensed assistive personnel required~~ in each patient care unit ~~in the hospital~~;

(b) ~~Be based on at least the~~ Evaluate the following criteria ~~on each patient care unit~~:

(i) Patient census, ~~including activity such as patient discharges, admissions, and transfers;~~
Patient turnover (discharges, admissions and transfers),
Patient acuity;
(ii) Level and type of patient care ~~intensity of all patients and nature of the care~~ to be delivered on each shift;
(iii) Skill level ~~mix~~, experience, and specialty certification or training of staff assigned to provide ~~those providing the~~ care;
(iv) ~~The need for~~ Specialized or intensive equipment;
(v) The physical layout and location ~~architecture and geography~~ of the ~~patient care~~ unit; and
(vii) The staffing guidelines of national ~~nursing and specialty nursing~~ organizations.

~~(c) Include appropriate limits on the use of agency and traveling nurses~~;
(d) Be consistent with the scope~~s~~ of practice for all licensed, certified or registered direct care staff ~~registered nurses and licensed practical nurses and the authorized duties of unlicensed assistive personnel~~;
(e) ~~Include adequate staffing to~~ Provide for staff time off, illnesses, meal and break time, and educational, health, and other leaves;
~~(f) Include a semiannual process for internal review by the staffing committee that ensures compliance with the staffing plan, provides for the review of incidents and staff concerns, and tracks staffing patterns, number of patients, and their acuity~~.

~~(3) The staffing plan must not diminish existing standards in law, rules, or the terms of an applicable collective bargaining agreement.~~

(4) Each hospital must ~~shall~~ implement and monitor ~~staff each patient care unit in accordance with it's~~ the staffing plan~~.~~ and make shift-to-shift adjustments ~~in staffing levels required by the plan may be made only if~~ based upon assessing patient needs and safety ~~by a registered nurse providing direct patient care on the patient care unit~~.

~~(5) Each hospital shall post the staffing plan for that patient care unit as required by this section on each patient care unit in the facility.~~

~~(6) Each hospital shall collaborate with its staffing committee in the development and implementation of its staffing plan~~.

~~(7) No hospital shall retaliate against or intimidate any employee for performing any duties or responsibilities in connection with participation on the staffing committee.~~

~~(8) No hospital shall retaliate against or intimidate any employee who notifies the staffing committee, the hospital administration, or the department that any schedule fails to meet with the posted staffing plan, or that the hospital has failed to develop or implement a staffing plan consistent with sections 1 through 7 of this section.~~

~~(9) Hospitals shall maintain accurate daily records showing:~~
~~(a) The number of patients present in each patient care unit at the end of each standard shift within the facility;~~
~~(b) The number of admissions, discharges, transfers, and observation patients in each patient care unit and each shift; and~~
~~(c) The number of registered nurses, licensed practical nurses, and unlicensed assistive personnel providing direct patient care in each patient care unit and shift within the facility.~~
~~(d) All records to be kept under this section must be maintained for a period of seven years be available upon request to the department and to the staffing committee.~~

~~(~~10) Hospitals must ~~shall~~ maintain and make available to each unit identified in the staffing plan ~~post~~ a list of qualified, on-call ~~nursing~~ staff ~~and nursing services~~ that may be called ~~to provide replacement staff~~ in the event of sickness, vacations, vacancies, and other absences ~~of nursing staff and that provides a sufficient number of replacement staff for the hospital on a regular basis~~.

~~(11) Semiannually, hospitals shall collect and submit to the department information regarding nurse staffing. In addition to the skill mix of registered nurse, licensed practical nurse, unlicensed assistive personnel and contract employees, and the nursing care house per patient per day, such information must also include at least three of the following National Voluntary Consensus Standards for Nursing Sensitive Care established by National Quality Forum:~~

~~a) Death among surgical inpatients with treatable serious complications (failure to rescue)~~
~~b) Pressure ulcer prevalence~~
~~c) Falls prevalence~~
~~d) Falls with injury~~
~~e) Restraint prevalence (vest and limb only)~~
~~f) Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients~~
~~g) Central line catheter-associated blood stream infection rate for ICU and high-risk nursery~~
~~h) (HRN) patients~~
~~i) Ventilator-associated pneumonia for ICU and HRN patients~~
~~j) Smoking cessation counseling for acute myocardial infarction~~
~~k) Smoking cessation counseling for heart failure~~
~~l) Smoking cessation counseling for pneumonia~~
~~m) Practice Environment Scale – Nursing Work Index (composite and five subscales)~~
~~n) Voluntary turnover~~

~~(12) The department shall investigate complaints of violations of this section~~.

~~(13) The department shall maintain for public inspection records of any civil penalties, administrative actions, or license suspensions or revocations imposed on hospitals under this section.~~

~~(14) The department shall conduct an annual random audit of not less than ten percent of all hospitals in this state solely to verify compliance with the requirements of this section. Surveys made by private accrediting organizations may not be used in lieu of the audit required under this subsection. The department shall compile and maintain for public inspection an annual report of the audit conducted under this subsection.~~

Substantiation: The Department does not favor the committee as it tends to be prescriptive and imposes a business structure on hospitals. The department has gone away from requiring or naming committees in lieu of policies, procedures and plans. These generally provide hospitals flexibility in matching service delivery to regulation while enabling the department to measure a hospital's compliance by the outcome of implementing and following the policy, procedure or plan. As suggested above the concept of a staffing plan and criteria for inclusion in such a plan fits the hospital licensing regulations. The department recommends including all direct care staff not only nurses into the plan. The intent is to more fully consider patient care, safety and outcome of care as relates to all staff who may serve a patient. The criteria included in a plan, represent minimum requirements and focus on patient safety.

Level of Support: Tabled Discussion – due to a clear division amongst participants regarding the ability to reach an acceptable modification that served all participants interests. The Department will assess and evaluate all information provided concerning the original proposal and/or comments and develop a proposed rule during the formal intent of rule making process (CR-102 filing with the Office of Code Reviser).

Modified proposal as follows:

Meeting discussion:

The Hospital Association (WSHA) recommended moving all of 2(b) to the interpretive guidelines. WSHA expressed concerns over 2(b) (vii) in that it may be difficult for small rural hospitals to meet the standards of national organizations; also, for how 2(e) was substantiated; and there is need for a definition for "direct care staff".

Suggested Modification- (a) "Staffing plan" means a document established by the hospital that defines a process individual units of the hospital will use to determine the number and type of direct care staff necessary to ~~safely~~ provide quality patient care.

Concern that rational for deleting paragraph (11) does not meet the mission of providing patient safety.

DOH: Striking paragraph (11) provides hospitals with the flexibility to determine the level of staff necessary to provide services.

DOH: What is the department expected to do with the information required in paragraph (11)? In terms of licensing a hospital, what purpose does this reporting serve? Additionally, the department views the proposed reporting criteria as redundant. Current law requires licensed hospitals to make all information available to the Department for purposes of determining compliance.

The group agreed to table this discussion until the end of the public meeting.

Proposal 004 - Comment 12 **Tabled Discussion**

Submitter: Nursing Commission
Section: 246-320-010
Recommendation: Disagree with this nurse staffing proposal. Some aspects are good such as staffing committees. This would require staffing plans to be submitted annually with DOH which includes "appropriate limits on agency and traveling nurses". This would be a hardship for certain hospitals and certain nurse specialty areas that are hard to recruit. Most hospitals find such contract labor much more expensive and desire to recruit permanent staff but have difficulty doing so.

#4 would require "shift to shift adjustments may be made only if based on the assessment by an RN providing direct patient care on the patient care unit". This would preclude RN House Supervisors from making staffing decisions based on the entire hospital census. Sometimes they have to rob Peter to pay Paul.
#11 also requires Hospitals to collect staffing data, semiannually and relate that to three of the National Voluntary Consensus Standards for Nursing Sensitive Care by National Quality Forum. For small hospitals this data may be too small of sample size to draw any conclusions.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Tabled Discussion - due to a clear division amongst participants regarding the ability to reach an acceptable modification that served all participants interests. The Department will assess and evaluate all information provided concerning the original proposal and/or comments and develop a proposed rule during the formal intent of rule making process (CR-102 filing with the Office of Code Reviser).

Modified proposal as follows:

Meeting discussion:

Proposal 004 - Comment 13 **Commentary**

Submitter: Patricia Di Egidio Tobis
Section: 246-320-010
Recommendation: Strongly support new language on safe nurse staffing as proposed. I've been an RN for over 33 yrs and continue to work full time. Recently I've been a pt both in a hospital and a nursing rehab center. Having proper staffing is essential based not only on pt census.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 007 - Comment 1 **Supported with Modification**

Submitter: Byron Plan
Section: 246-320-010
Recommendation: Proposal 7 was supported as written & 8 was supported in principle. These relate to the same definition. What is needed is a definition of "air flow" so operationally hospital & DOH staff can determine if a potential for contamination of adjacent rooms or areas exists.

"Air flow" means the direction of air movement between adjacent rooms or areas within a hospital.

"Positive air flow" means air moves out from or away from a room or area.

"Negative air flow" means air moves into or towards a room or area.

Substantiation: This is necessary to determine the potential for contamination of rooms or areas. It is in keeping with the concept of using air flow to protect clean or sterile portions of a hospital from dirty/contaminated areas. Air flow/movement is also justified as an infection control mechanism.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

The definition should be consistent with the AIA Guidelines.

Meeting discussion: Geoff Glass noted that this should not be included in the definitions of the WAC as it is often used as a retroactive requirement. Mr. Glass suggested the definition be consistent with the AIA Guidelines and the suggestion was agreed to by the majority of participants. Mike Kelley also noted his experiences with this definition being applied retroactively during site surveys.

Concerns were expressed regarding how the definition would be operationally applied/enforced.

Proposal 007 - Comment 2 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Support, this is use of the AIA guidelines for construction

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 009 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Support, this is another addressing the use of individual LIP order for protocols.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only. Concerns that there may need to be a separate definition for "standing order" vs. "protocols."

Proposal 011 - Comment 1 **Commentary**

Submitter: Byron Plan
Section: 246-320-025
Recommendation: DOH agrees with the modification made at the March meeting. JCAHO and AOA accredited hospitals are to notify the Department within 30 calendar days of receiving an accreditation decision.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 011 - Comment 2 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH proposes changing the licensing survey to every 18 months. JCAHO or AOA survey can replace the DOH survey. New language for announced survey due to complaint investigation due to patient care or safety. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 012 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Would require DOH post in the website, the results of the findings of any complaint or investigation that result in the finding of deficiencies. These may be obtained from DOH already???

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: Participants asked if this type of information is publicly available. Department representatives confirmed that **y**es, these documents/information are available through requesting public disclosure. This comment did not propose a change and therefore is taken as advisory only.

Proposal 012 – Comment 2 **Supported as Proposed**

Submitter: Tom Granger
Section: 246-320-
Recommendation: As the original submitter, SEIU is withdrawing the proposal for consideration.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as proposed

Modified proposal as follows:

Meeting discussion: The group supported the withdrawal of the proponents original proposal.

Proposal 013 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Changes fire and life safety surveys to include coordinating with the state fire marshal and local agencies. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 014 - Comment 1 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-New Section
Recommendation: (2) sub letter, new language) Compliance with the on-site survey conducted by the State Fire Marshal as provided in chapter 70.41.080.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 014 - Comment 2 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Changes in fee and application process. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 015 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Discusses actions and responsibilities of DOH with regards to licensing. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 015 - Comment 2 **Supported with Modification**

Submitter: Brenda Suiter
Section: 246-320-New Section
Recommendation: (4)(f) Respond within ~~30~~ 15 days of a hospital's request for an interpretation as provided for in section 065 of this chapter.

Substantiation: The Department needs to increase the timeliness of their response to requests for interpretations of the rules. This change makes the timeline for interpretation consistent with the timeline for requests for exemption (4)(e) which is also 15 days.

Whether or not other changes to the interpretations and exemptions rules need to also be discussed during the June 21st meeting.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

(4)(f) Respond within 30 calendar days of a hospital's request for an interpretation as provided for in section 065 of this chapter.

Editorially add 30 calendar days to (4)(e)

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 015 - Comment 3 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-New section
Recommendation: Discussion during March meeting asked for clarification of DOH complaint and adverse event investigation. DOH to consider a definition of well being.

(c) Conduct an investigation of every complaint against a hospital and adverse event reported by a hospital that concerns patient ~~safety and~~ well-being;

"Well being" means free from actual or potential harm, abuse, neglect, unintended injury, death, serious disability or illness.

In response to question about Department informing hospitals of an investigation, we do this for adverse event investigations and state-only investigations. DOH cannot announce a Medicare investigation,

Substantiation: The term "well being" needs clarification/definition so hospital and the Department will know what can lead to an investigation. Language changed (deleted safety and) to accurately state what the law requires in RCW 70.41.380.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: DOH: Potential harm is addressed in the Federal Statutes.

Proposal 016 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Revisions by DOH re text changes. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 016 - Comment 2 **Supported with Modification**

Submitter: Brenda Suiter
Section: 246-320-065
Recommendation: (2)(iii) If appropriate, describe how and why the alternative will not jeopardize patient safety, health and well-being.

Substantiation: Exemption requests that do not involve patient safety, health and well-being should not have to justify why they won't affect them.

Other ways to simplify the exemption process need to also be discussed during the June 21st meeting. We need to assure that this new language does not discourage hospitals from submitting exemption requests.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

Except when related to patient safety, health, or well being, ~~If appropriate~~ describe how and why the alternative will not jeopardize patient safety, health and well-being.

Meeting discussion: DOH: Who defines what is "appropriate"? The group decided to strike the reference to appropriate and agreed to the above listed modification.

Proposal 016 - Comment 3 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-
Recommendation: During March meeting, DOH asked to consider clarifying when an exemption would be granted. This would be a new subsection/paragraph to the "new" section proposed as part of proposal 15.

The Department may issue an exemption or the use of an alternative material, design or method upon determining that the material requested in section 065 indicates there is no jeopardy to patient safety, health or well being.

Substantiation: Clarifies criteria for DOH to grant an exemption or alternative.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 017 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-085
Recommendation: Revisions by DOH re text changes. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 018 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-125
Recommendation: DOH to establish and review governing polices to include requirements for reporting practitioners and informing patients of any unanticipated outcomes (41.70 RCW). For this to work, a definition of an unanticipated outcome is needed. RCW 41.70 does NOT include that. Wide variation in thought about what is an unanticipated outcome.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 018 - Comment 2 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-125
Recommendation: Revise wording (add correct RCW cite).

(2) Establish and review governing authority policies to include:
requirements for reporting practitioners in accordance with 70.41.210 RCW and informing patients of any unanticipated outcomes in accordance with chapter 70.41.380 RCW,
promote performance improvement, and
provide for organizational management and planning;

Move the definition of practitioner to this section.

For the purposes of this section, practitioner means pharmacists as defined in chapter 18.64 RCW; advanced registered nurse practitioners as defined in chapter 18.79 RCW; dentists as defined in chapter 18.32 RCW; naturopaths as defined in chapter 18.36A RCW; optometrists as defined in chapter 18.53 RCW; osteopathic physicians and surgeons as defined in chapter 18.57 RCW; osteopathic physician [physicians'] assistants as defined in chapter 18.57A RCW; physicians as defined in chapter 18.71 RCW; physician assistants as defined in chapter 18.71A RCW; podiatric physicians and surgeons as defined in chapter 18.22 RCW; and psychologists as defined in chapter 18.83 RCW

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 019 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Would require each hospitals' bylaws to address governing authority meetings and make public comment available at each meeting. Also requires submittal to DOH each hospital's bylaws.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 019 - Comment 2 **Supported as Proposed**

Submitter: Tom Granger
Section: 246-320-
Recommendation: As the original submitter, SEIU is withdrawing the proposal for consideration.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 020 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-145
Recommendation: DOH proposal to expand adverse events to be reported. This list is quite extensive. Some I would support, some are already reportable thru the safe medical device act, JCAHO, etc.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 020 - Comment 2 **Supported with Modification**

Submitter: Byron Plan
Section: 246-320-145
Recommendation: Clarify the list of practitioners who are to be reported to the DOH**.**

For the purposes of this section, practitioner means pharmacists as defined in chapter 18.64 RCW; advanced registered nurse practitioners as defined in chapter 18.79 RCW; dentists as defined in chapter 18.32 RCW; naturopaths as defined in chapter 18.36A RCW; optometrists as defined in chapter 18.53 RCW; osteopathic physicians and surgeons as defined in chapter 18.57 RCW; osteopathic physician [physicians'] assistants as defined in chapter 18.57A RCW; physicians as defined in chapter 18.71 RCW; physician assistants as defined in chapter 18.71A RCW; podiatric physicians and surgeons as defined in chapter 18.22 RCW; and psychologists as defined in chapter 18.83 RCW

Replace the list of serious events in the proposal and replace with a table form including a guideline.

~~Surgical events:~~
~~Surgery performed on the wrong body part;~~
~~Surgery performed on the wrong patient;~~
~~Wrong surgical procedure performed on a patient;~~
~~Retention of a foreign object in a patient after surgery or other procedure;~~
~~Intraoperative or immediately post-operative death in an ASA Class 1 patient;~~

~~Product or device events:~~
~~Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the~~

~~hospital;~~
~~Patient death or serious disability associated with the use or function of a device in patient care which the device is used or functions other then intended;~~
~~Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a hospital;~~

~~Patient protection events:~~
~~Infant discharged to wrong person;~~
~~Patient death or serious disability associated with a patient elopement (disappearance) for more than four hours;~~
~~Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a hospital;~~

~~Care management events:~~
~~Patient death or serious disability associated with a medication error such as but not limited too errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, wrong route of administration;~~
~~Patient death or serious disability associated with a hemolytic reaction due to administration of ABO incompatible blood or blood products;~~
~~Maternal death or serious disability associated with labor or delivery in a low risk pregnancy while being cared for in a hospital;~~
~~Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital;~~
~~Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in a neonate;~~
~~Stage 3 or 4 pressure ulcers acquired after admission to the hospital;~~
~~Patient death or serious disability due to spinal manipulative therapy;~~

~~Environmental events:~~
~~Patient death or serious disability associated with an electric shock while being cared for in the hospital;~~
~~Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains wrong gas or is contaminated by toxic substances;~~
~~Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital;~~
~~Patient death associated with a fall while being cared for in the hospital;~~
~~Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the hospital;~~

~~Criminal events:~~
~~Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;~~
~~Abduction of a patient of any age;~~
~~Sexual assault on a patient within or on the grounds of a hospital; and~~
~~Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of the hospital.~~

ADVERSE EVENT	GUIDANCE
1. Surgery performed on the wrong body part	Defined as a surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose existence precludes obtaining informed consent. Surgery includes endoscopies & other invasive procedures.
2. Surgery performed on the wrong patient.	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies & other invasive procedures.
3. Wrong surgical procedure performed on a patient.	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or

	whose existence precludes obtaining informed consent. Surgery includes endoscopies & other invasive procedures.
4. Retention of a foreign object in a patient after surgery or other procedure.	Excludes objects intentionally implanted as part of a planned intervention & objects present prior to surgery that were intentionally retained.
5. Intraoperative or immediately post-operative death in an ASA Class 1 patient.	Includes all ASA Class 1 patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means with 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.	Includes but not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
9. Infant discharged to wrong person.	
10. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours.	Excludes events involving competent adults.
11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility.	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.
12. Patient death or serious disability associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration).	Excludes reasonable differences in clinical judgment on drug selection and dose.
13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.	
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the healthcare facility.	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.	
16. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia neonates.	Hyperbilirubinimia is defined as bilirubin levels > 30mg/dl. Neonates refers to the first 28 days of life.
17. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
18. Patient death or serious disability due to spinal manipulative therapy.	
19. Patient death or serious disability associated with electric shock while being cared for in a	Excludes events involving planned treatments such as electric countershock.

healthcare facility.	
20. Any incident in which a line designed for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.	
21. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.	
22. Patient death associated with a fall while being cared for in a healthcare facility.	
23.Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.	
24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.	
25. Abduction of a patient of any age.	
26. Sexual assault on a patient within or on the grounds of a healthcare facility.	
27. Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of a healthcare facility.	

Define serious disability.

"Serious disability means a physical or mental impairment that substantially limits one or more of the major life activities of a patient (based on the NQF definition)

Revise the notification subsection to be consistent with the newly passed legislation (HB 2292)

~~(~~11)~~-~~Notify ~~Provide written notification to~~ the department as required in subsection (10)~~ of this section~~ within~~-~~forty-eight (48) hours ~~two administrative business days~~ of confirmation by the hospital~~ confirming~~ that the adverse event has occurred ~~leaders learning of the confirmed event~~. The notice to the department is to be made using the internet-based reporting system. ~~The hospital is encouraged to confirm these events through a review or assessment by the hospital quality improvement or risk management processes. Each notice to the department:~~

~~(after (11) (a) (iii)) A summary discussion of:~~
~~What lead up to or caused the event to occur;~~
~~The steps taken to correct the problem(s) that lead to the event;~~
~~The date for implementing the corrections to the problem(s); and~~
~~The process used to monitor the effectiveness of the correction..~~

(12) Hospital must conduct a root cause analysis of each adverse event. The analysis must follow the root cause analysis procedures and methodologies of:
(a) the joint commission on the accreditation of health care organizations, or
(b) the department of veterans affairs national center for patient safety.

(13) Hospital must create and implement a corrective action plan for each adverse event that is consistent with the findings of the root cause analysis. Each corrective action plan must include:
(a) How each finding(s) will be addressed and corrected,
(b) When each correction will be completed,
(c) Who is responsible to make the correction(s)
(d) What action(s) will be taken to prevent each finding(s) from reoccurring, and
(e) A monitoring schedule for assessing the effectiveness of the action plan including who is responsible for the monitoring schedule.

(14) If a hospital determines there is no need to create a corrective action plan for a particular adverse event, the hospital must create a written explanation of the reason(s) for not taking corrective action.

(15) Within forty-five days after confirming an adverse event has occurred, hospital must complete and submit a report using the internet-based adverse events and incident reporting system.

Substantiation: Clarify the list of practitioners who are to be reported to the DOH. This list appears in law (RCW 70.41.210) and applies only to the reporting of unprofessional conduct. Placing the list in this section makes it easy for hospitals to know which practitioners are to be reported to DOH.

Replace the list of serious events in the proposal and replace with a table form including a guideline. The original proposal was written before the law changed. This table and guideline comes from the NQF 2002 report.

Define serious disability. This term appears numerous times in the adverse event table. During the March meeting DOH was asked to consider defining the term. This is intended as a starting point for discussion and to decide if a definition is needed.

Revise the notification subsection to be consistent with the newly passed legislation (HB 2292). The original proposal was written before the law changed as follows: "…must conduct a root cause analysis of the event, describe the corrective action plan that will be implemented consistent with the findings of the analysis, or provide an explanation of any reasons for not taking corrective action. The department shall adopt rules … related to the form and content of the root cause analysis and corrective action plan. In developing the rules, consideration shall be given to existing standards for root cause analysis or corrective action plans adopted by the joint commission on accreditation of health care facilities and other national or governmental entities." The bill also stipulates, "… shall notify the department of health regarding the occurrence of any adverse event and file a subsequent report … report must be submitted to the department within forty-five days after confirmation by the medical facility that an adverse event has occurred. The notification and report shall be submitted to the department using the internet-based system …"

The internet-based system is not available. DOH is in the process of identifying potential organizations/vendors that could provide the electronic reporting system. Once a vendor is selected, they will work with DOH and hospitals on what the reporting system looks like and what information will be collected.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

Add: 12(c) "or another nationally recognized root cause analysis methodology or found acceptable by the Department of Health.

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 020 - Comment 3 **Supported as Proposed**

Submitter: Dept. of Health, Health Professions Quality Assurance Division
Section: 246-320-145
Recommendation: Proposal 020 (bottom of page 31 of 126): "i.e. battery": battery is not equivalent to physical assault. Suggest leaving this phrase out entirely & just stick with physical assault.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: DOH: Byron Plan comment: DOH will verify that the proposed definition is consistent with other standards.

Note: Byron Plan reported after the meeting that the proposed definition is consistent with current law and additional clarification will be provided through the development of interpretive guidelines.

Proposal 021 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-145
Recommendation: DOH to make public on the website each instance of hospital's notification of a patient or patient's family of any unanticipated outcome as required by 41.70 RCW. There is not a definition of unanticipated outcome and not all of these are hospital errors. Disagree.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 021 – Comment 2 **Supported as Proposed**

Submitter: Tom Granger
Section: 246-320-
Recommendation: As the original submitter, SEIU is withdrawing the original proposal for consideration.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 022 - Comment 1 **Commentary**

Submitter: Jean Erickson, RN
Section: 246-320-145
Recommendation: I feel it is important to investigate the staffing, both numbers and expertise level, when investigating adverse events, but I am concerned about making the initial reporting form so lengthy and complicated that events do not get reported. I myself have two half-finished (out of three) unsafe staffing reports in my files from years ago. The reports asked for information I would have had to go to medical records for and were so lengthy that I never finished them. Remember, I all ready was over worked, no breaks, and overtime because of the unsafe staffing. I was working so many hours that I just didn't get the reports finished. Fortunately, the situation was finally resolved when turned into the state authorities. However, simpler, shorter initial event reporting would have helped greatly. The "ins and outs" can be part of the following investigation.
Thanks,

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 2 **Commentary**

Submitter: Kathleen Gilbertson-Stimpfle
Section: 246-320-145
Recommendation: Strongly support revised language as proposed to include information on nurse staffing and overtime information.

Substantiation: I belong to the Employee Safety Committee at Sacred Heart Medical Center, Spokane, WA. I provide direct bedside care as an RN.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 3 **Commentary**

Submitter: Julia Weinberg
Section: 246-320-145
Recommendation: Strongly support new language on safe nursing staffing as proposed.

Substantiation: As a Registered Nurse, my responsibility to the patients I care for, is to provide competent safe care in an environment which is also safe for both the patient and myself. I expect my employer to provide what I need in order to meet the care needs of my patients and an environment which is safe and supportive for us both. The nursing shortage and less healthcare dollars due to decreases of Medicare and Medicaid, lack of health insurance, or no insurance by the patients, in my experience, I witness on a day-to-day, staffing shortages and nurses working overtime on a regular basis. However, when an adverse event happens, the staffing pattern or shortage nor the overtime issues, do not seem to be taken into account as to why the adverse even happened. There is much research today that supports, that an increase in error and adverse outcomes can occur due to these two very important critical factors. Yet, the employer does not focus, or chooses not to focus, if they did, then they would be accountable for contributing to the adverse event. As an RN I am accountable for the care I give or do not give. Employers need to be held more accountable for staffing appropriately and providing rest time and having only minimal OVT and not routine OVT used for staffing. This proposal puts more focus on these critical issues which should be a big part of the equation as a root-cause analysis is done.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 4 **Commentary**

Submitter: Patricia Di Egidio-Tobis
Section: 246-320-145
Recommendation: Strongly support revised language as proposed to include information on nurse staffing and overtime information. Proper reporting of adverse events should increase pt safety as we learn from our mistakes.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 5 **Commentary**

Submitter: Nursing Commission
Section: 246-320-145
Recommendation: With each report to DOH of an unanticipated outcome, the hospital must also report on nurse staffing conditions. Again, not all unanticipated outcomes are errors or relate to nurse staffing.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 6 **Commentary**

Submitter: Cathy & Patricia, Di Egidio Tobis, & Joyce Daniels
Section: 246-320-145
Recommendation: Strongly support revised language as proposed to include information on nurse staffing and overtime information.
Note: *The three submitters above provided individual comments. The information provided in section 3 & 4 were typically the same, and therefore combined.*

Substantiation: (submitted by Patricia Di Egidio Tobis) I've been a nurse for almost 35 years. I strongly support safe staffing especially as the nursing shortage continues and having guidelines to follow will have a direct bearing on this portion of the revision.
(submitted by Joyce Daniels) I strongly support this proposal in order to give quality patient care

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 7 **Commentary**

Submitter: Rep. Dawn Morrell, RN
Section: 246-320-145
Recommendation: I strongly support this comment as submitted and suggest that DOH include it in the rule revision.

Substantiation: This language would help to identify if errors are caused by lack of staffing which in currently not taken into account.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 022 - Comment 8 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-145
Recommendation: Do not support specifying what hospitals must report to the Department of Health. This needs to be determined as part of the internet-based reporting system.

Substantiation: The detail of what will be included in notice to the department will be determined, through a separate public process, as part of the internet-based reporting system required by law (HB 2292). DOH and the contractor hired to develop that system will meet with hospitals and other interested parties as to what is included in the 48 notice and the 45 day report.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: Comment #8 Only -5 Not supported/ 8 Supported. Note: Comments #1-#7 - 8 Not Supported/ 6 Supported

Proposal 023 - Comment 1 **Withdrawn**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH to report as much as possible on their website about unanticipated outcomes as allowed by law. Disagree

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Comment Withdrawn

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 023 – Comment 2 **Supported as Proposed**

Submitter: Tom Granger
Section: 246-320-
Recommendation: As the original submitter, SEIU is withdrawing the original proposal for consideration.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 024 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Changes in requirement to report suspected abuse to local police within 48 hours. Brings this WAC current with RCW 26.44. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 025 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Changes in text from DOH. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 026 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Changes in text from DOH. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 026 - Comment 2 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-185
Recommendation: For clarity, include the list of practitioners found in 70.41.210.

Reporting process for practitioners in accordance with RCW 70.41.210.

For the purposes of this section, practitioner means pharmacists as defined in chapter 18.64 RCW; advanced registered nurse practitioners as defined in chapter 18.79 RCW; dentists as defined in chapter 18.32 RCW; naturopaths as defined in chapter 18.36A RCW; optometrists as defined in chapter 18.53 RCW; osteopathic physicians and surgeons as defined in chapter 18.57 RCW; osteopathic physician [physicians'] assistants as defined in chapter 18.57A RCW; physicians as defined in chapter 18.71 RCW; physician assistants as defined in chapter 18.71A RCW; podiatric physicians and surgeons as defined in chapter 18.22 RCW; and psychologists as defined in chapter 18.83 RCW

Recommend deleting term “licensed independent practitioners”

(2) Include licensed physicians~~, licensed independent practitioners~~ and ~~may include~~ other individuals granted privileges by the governing authority to provide patient care services; and

Reporting process for practitioners in accordance with RCW 70.41.210.

For the purposes of this section, practitioner means pharmacists as defined in chapter 18.64 RCW; advanced registered nurse practitioners as defined in chapter 18.79 RCW; dentists as defined in chapter 18.32 RCW; naturopaths as defined in chapter 18.36A RCW; optometrists as defined in chapter 18.53 RCW; osteopathic physicians and surgeons as defined in chapter 18.57 RCW; osteopathic physician [physicians'] assistants as defined in chapter 18.57A RCW; physicians as defined in chapter 18.71 RCW; physician assistants as defined in chapter 18.71A RCW; podiatric physicians and surgeons as defined in chapter 18.22 RCW; and psychologists as defined in chapter 18.83 RCW

Recommend deleting term “licensed independent practitioners”

(2) Include licensed physicians~~, licensed independent practitioners~~ and ~~may include~~ other individuals granted privileges by the governing authority to provide patient care services; and

Substantiation: Adding the list of practitioners makes it clear who must be reported. This is consistent with proposals 18 & 20.

DOH does not see the need to differentiate who is granted privileges in a hospital. Each hospital establishes its own credential process and the authorizations associated with each individuals credential/privilege. This appeared in the original proposal as necessary for authorizing “standing orders” and “protocols”. As stated in proposal 1, DOH recommends deleting this suggestion.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 027 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Changes in text from DOH. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 028 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-225
Recommendation: Changes in text from DOH. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 028 - Comment 2 **Supported with Modification**

Submitter: Byron Plan
Section: 246-320-225
Recommendation: Based on discussion at the March meeting, DOH was asked to provide a definition of "near miss".

"Near miss" means an event, action or incident that could have had an adverse consequences for a patient but did not and is indistinguishable from a fully alleged adverse event.

"Near miss" means an event or circumstance which has the potential to cause serious physical or psychological injury, death, or harm but did not actualize due to chance, corrective action or timely intervention.

"Near miss" means an event or situation that did not produce patient injury or harm, but only because of chance

"Near miss" means an incident, event or situation that could result in patient injury, harm or death but didn't

"Near miss" means an incident, event or situation that could have resulted in negative consequences but didn't

"Near miss" means an incident, event or situation in which an accident almost happened but was avoided

"Near miss" means an event where no harm, loss, injury, damage or death was suffered

Substantiation: The list of possible definitions comes from a search of the internet. Recommend group discussion with regards to which one is acceptable.

Level of Support: Support with Modification

Modified proposal as follows: Accept definition as follows:

Definition of "Near miss" means an event or circumstance which has the potential to cause serious ~~physical or psychological~~ injury, death, or harm but did not actualize due to chance, corrective action or timely intervention.

Meeting discussion: See the groups modification and decision on which definition of "near miss" was acceptable.

Proposal 029 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-245
Recommendation: Changes in text from DOH. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 030 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-265
Recommendation: DOH to adopt APIC guidelines. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 030 & 031 - Comment 2 **Not Supported**

Submitter: Byron Plan
Section: 246-320-265
Recommendation: Modify the original proposal to clearly identify that these policies and procedures apply to patient care areas.

(3) Adopt and implement written policies and procedures consistent with the published guidelines of the centers for disease control and prevention (CDC) and the Association for Professionals in Infection Control & Epidemiology (APIC) regarding infection control in hospitals, to guide the staff. ~~Where appropriate~~, Policies and procedures are specific to the patient care ~~service~~ areas and address:

Modify the original proposal to have hospital address humidity levels.

(j) Barrier and transmission precautions,

(new letter) hospital response to excessively high (>85%) and excessively low (<15%) ~~including maintaining~~ humidity levels ~~in accordance with APIC guidelines~~; and

(k) Pharmacy and therapeutics; ~~and~~

Substantiation: Concern raised during the March meeting that humidity should not be addressed in this section of the regulations. DOH believes there is a need for hospitals to consider actions to take if a facility experiences excessively high or low humidity levels. The policies & procedures are to guide the hospital when facing such conditions during the day-to-day operation of the facility.

Level of Support: Not Supported

Modified proposal as follows: Revise text as follows:

The group suggested that DOH insert language that ties the requirement to a specific outcome and provide hospitals flexibility to develop a plan.

Meeting discussion: Byron Plan noted that NFPA 99, Standard for Healthcare Facilities is required by CMS to be met for new and existing construction. Chad Beebe noted that since the elimination of virtually all flammable anesthetics, that low humidity is no longer a concern. It was commented that the unique climate of Washington does not require the need to install humidification devices. The devices are often not used and costly to maintain. Mr. Beebe also noted that in Washington we vary rarely experience high humidity limits and generally high humidity is controlled through any air cooling system. Mr. Beebe also noted that in his conversations with Judene Bartley, Epidemioligist, and Infection Control Consultant for APIC and CDC there is little concern over humidification and that low humidification, may be a surgical preference, and can be accommodated for patients by the use of masks, and high humidity is only problematic for infection control when condensation forms. Geoff Glass noted his concern that the department was going to require facilities to continually monitor their OR's so that they could show the survey staff their records. It was also noted that the surveyors have been inconsistent in their interpretation, and have required the installation of humidification devices. If there is no evidence based need for a higher or lower limit, then why include it in the rules. See additional comments on this proposal received by meeting participants.

Proposal 032 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-285
Recommendation: DOH text revision. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 033 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH to post on the website each hospital having experienced one of its frequent problems. Too vague. Disagree.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 033 – Comment 2 **Supported as Proposed**

Submitter: Tom Granger
Section: 246-320-
Recommendation: As the original submitter, SEIU is withdrawing the original proposal for consideration.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 033 - Comment 3 **Withdrawn**

Submitter: Byron Plan
Section: 246-320-045
Recommendation: Recommend deleting this requirement.

~~The agency shall identify and post to its website the name of each hospital having experienced one of the frequent problems. The posting shall include a brief description of the frequent problem and the date on which the frequent problem occurred at each hospital.~~

Substantiation: DOH does not believe this is the place to require posting of specific information. The hospital rules are intended to address hospital regulatory issues and the departments' responsibility to enforce those regulations. The hospital law (RCW 70.41.045(2) directs the agency to "… post to its agency web site a list of the most frequent problems identified in its hospital surveys or audits along with information on how to avoid or address the identified problems, and a person within the agency that a hospital may contact with questions or for further assistance." The requirement is placed on the department and not a hospital.

Level of Support: Withdrawn

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 034 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-325
Recommendation: DOH proposal to bring laboratory staff into line with other WACS and RCWs. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 035 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-345
Recommendation**:** DOH proposal to expand inpatient assessment to include: risk for falls, pressure ulcers, pain and medication use, use of restraints, mental status. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 035 - Comment 2 **Not Supported**

Submitter: Byron Plan
Section: 246-320-345
Recommendation: Retain proposed wording. On going assessment, knowledge and documentation of these items is one method for implementing and ensuring safe patient outcomes. Falls, pressure ulcers pain and medication management are all now included in the 27 adverse events.

(new language) Periodic patient assessment for risk of falls, skin condition, risk for pressure ulcers, pain and medication use, therapeutic effects and side or adverse effects

Clarify definition of living will. Legal context for this appears in chapter 70.122, the natural death act of Washington.

"Living will" or "advance directive" means a written document that indicates a patients' choice with regard to specific treatment, medication, resuscitation, tissue/organ donation or other medical care.

"Living will" or "advance directive" means a written instruction recognized by state law relating to the provision or non-provision of health care when a patient is incapacitated.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Not Supported

Modified proposal as follows:

Meeting discussion: The group decided that a definition for "living will" was not needed.

Proposal 036 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-365
Recommendation: DOH text changes re wording for Level one, two, and three nursery. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 036 - Comment 2 **Supported as Proposed**

Submitter: Gail T. McGaffick for Washington Association of Nurse Anesthetists
Section: 246-320-365
Recommendation: Please make the following changes:

"To ~~anesthesiology~~ anesthesia services and qualified ~~anesthesiology~~ anesthesia practitioner; and"

Substantiation: The language as written is not consistent with current hospital rules, which use the provider neutral language of "anesthesia services" (WAC 246-320-345(5)(p), and "anesthesia practitioner" (WAC 246-320-365(9)(b). We support provider neutral language.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 037 - Comment 1 **Supported with Modification**

Submitter: 177 responses to proposal 037 were received. The recommendation and substantiation information for these responses was typically the same. Please see below for any additional substantiation received. [A complete list of these proponents with contact information is available upon request.]
Section: 246-320-365
Recommendation: Assure ~~sufficient number of personnel to ensure~~ that a registered nurse qualified by training and experience ~~is present in the operating room and~~ functions as the circulating nurse throughout every surgical or invasive procedure in the operating room.

Substantiation: Every patient undergoing a surgical procedure is entitled to safe and quality nursing care. Currently, there is no law or regulation in Washington that requires a healthcare professional to continually assess and manage patient care needs during surgical procedures.

The proposed rule, as revised would require that a registered nurse (RN) be present during every operative or invasive procedure to circulate and serve as the single patient advocate in the operating room. Currently, approximately twenty-two (22) states require that the RN circulate throughout each operative procedure. WA state perioperative nurses with

support from the Association of Perioperative Registered Nurses (AORN) strongly encourages Washington to join with the many other states in supporting and ensuring optimal patient safety in the operating room by requiring an RN circulator.

- Sheryl Jump submitted the following additional substantiation: RN's are licensed and have some type of recourse if inadequate. Techs have minimal training. They are trained in anatomy, but not physiology or function. Patient injuries can occur because of improper positioning. RN's are trained in airway management to assist anesthesia. RN's have training in the whole body, not the sum of its parts.
- Linda DeCarlo submitted the following additional substantiation: An RN has the ability to assess the patient's needs and implement the care needed. RN's are trained to assess all physical systems including psychosocial needs. The training is unique to the RN compared to physicians and technicians. This holistic approach is why nurses are seen at the patient's advocate.
- Kari Ashcraft submitted the following additional substantiation: do not delete anything
- Elizabeth Hendershott submitted the following addition substantiation: Having prior experience with a hospital that used (1) RN to cover 2 O.R.s I can testify to the seriousness of this proposal.

1) When non-licensed are give RN "like" duties it is very easy for the line to be crossed. The ultimate responsibility lies on the RN.
2) Non-licensed personnel don't have as much at stake. Surgery is very serious and life threatening.
3) Circulating nurses need to be technologically savvy as well as strong medicine skills. Routine cases can turn emergent without warning.
4) RN burnout is high, why increase the stress?

- Cheryl Linder submitted the following additional substantiation: I believe that for the safety of the patient, the circulating nurse should always be a qualified Registered Nurse for all surgical or invasive procedures. I support the above proposal but would like to see the phrase "in the operating room" deleted. Invasive procedures take place in other areas in addition to the operating room, such as cath labs and endoscopic labs, GI labs, etc; all these patients deserve to have a qualified RN as their circulating nurse.
- Cheryl Gonzalez submitted the following additional substantiation: As an RN that works full-time in the O.R., I know the skill level and expertise a nurse must have to fulfill the role of a circulator. The roll requires knowledge of all specialties in the medical field and be able to perform in a capacity that most people do not understand unless they have worked in an O.R. We are required to participate in continuous education courses in to keep up with new technology and innovative surgical techniques. It is a responsibility and desire to be the best that only a nurse could ever fulfill. For the safety of our patients; For the consistency of patient care; and, For the satisfaction of knowing our patients feel safe with a nurse at their side. Please think about what could potentially happen if nurses were no longer at our patient's side. The importance or revising this Proposal (246-320-365) goes far beyond than just words on paper.
- Hollee Mickelson submitted the following additional substantiation: Time and time again, studies show that RNs increase patient safety and thereby decrease costs. Without RNs, liability skyrockets.
- Peggy Dotlich submitted the following addition substantiation: RN training provides for critical thinking. The focus is on the care of the pt – not technical skills. As the technology is expanded in the O.R. environment, the pt can get lost. Pt safety is JCAHO's 2006 focus – only the RN can assure and provide for this effectively.
- Kelly McGinnis submitted the following additional substantiation: I have been a practicing anesthesiologist for 16 years. During my training and career circulating OR nurses have always been RN's who have responsibility for only 1 room.
  I believe having an RN circulating in the OR is an indispensable contribution to patient care. There are certainly some exceptional techs that I've run across during my years, but, overall, the RN has the educational background and clinical judgment to assess what can be a rapidly changing situation in an OR. More than once, I've had an RN circulator come over and ask if I needed anything. They'd observed me starting to make interventions and glanced at the patient's vital signs. Surgeons and techs were focused on other issues. More than once they've just gone and gotten more equipment and come to tell me that something I made need is just outside the door.
  I cannot imagine that standard of care in an operating room could be the same if an RN were not the circulating nurse.
- Mary McCourtie submitted the following additional substantiation: All surgical patients experience altered states of consciousness and/or diminished reflexes. Having an RN circulator present in the room for every procedure is paramount to pt safety in this critical care, high liability area.

- John Fenoli submitted the following additional substantiation: As a former EMT and son of a surgical room nurse, I very strongly urge the State not to allow persons of lower or lesser competence to "fill in" in surgical wards. If you child was getting surgery, what qualifications would you want the staff to have?
- Clara Welter submitted the following additional substantiation: The RN circulator can predict, prevent and manage adverse outcomes. This is a positive patient safety issue.
- Jan Cebular submitted the following additional substantiation: In support of revised proposal.
- Terry Dyer submitted the following additional substantiation: As a patient advocate, while the patient is unable to speak for themselves, the RN has the training and education to assure that the patient's needs are met, help with intubation, positioning, and sterile proceeds are done properly.
- Kimberly DuBore submitted the following additional substantiation: The above statement, in which I fully support, would be in the best interests of our pts. and their families. RN's in the operating room have specialized training in pt. safety and peri-operative welfare.
- Bev Brown submitted the following additional substantiation: R.N.'s are taught patient care throughout their training & on the job. R.N.'s are patient advocates. In all my 30 some years of O.R. experience there has always been a registered nurse in the O.R. to aid, help & understand the patients' needs.
- Sean Sweeney submitted the following additional substantiation: I fully support the above revised proposal.
- Miranda Shumate submitted the following additional substantiation: I agree with the above statement. The position of OR circulating nurse is a complicated job and the individual in that position should be a well-trained RN with advanced training in ACLS & PALS as well as having exceptional IV skills and advance knowledge in Anatomy, Physiology and disease process.
- Monica Lindquist-Cain submitted the following additional substantiation: I agree with the wording in the above proposal.
- Linda Roths submitted the following additional substantiation: I have been a patient in this OR department multiple times and other hospitals in the Olympia area. I would be hesitant to have surgery without the care of a trained RN in the room.
- Carleen Stern submitted the following additional substantiation: In and emergency a qualified nurse is needed for ALS & dosages of drugs which a tech is not. I also feel a nurse is more compassionate & caring for the patient. She is the patient advocate.
- Dawn Erickson submitted the following additional substantiation: I support revised proposal for a RN to be circulating nurse in the OR. An RN has been trained to understand the complexities of the OR.
- Brenda Stopsen submitted the following additional substantiation: I support the above statement.
- Debra Brogan submitted the following additional substantiation: I am in full support of this proposal. As an RN it is my belief that there should always be an RN circulator in OR cases. We should be doing all we can to provide educated, high quality care.
- Ivy Harju-Slag submitted the following additional substantiation: I support that a registered nurse be present throughout each surgical or invasive procedure in the Operating Room. The Registered nurse has the education and training to be the second set of eyes and ears for the anesthesiologist; is able to advocate for the patient who has no voice and have the ability to monitor all patient systems and their interrelationship.
- Pauline Young submitted the following additional substantiation: I'm in support of the above proposal.
- Carol Earley submitted the following additional substantiation: I fully support the above revised proposal language.
- Kathy Jamsgard submitted the following additional substantiation: I support the revised statement of the proposal.
- Williams Hofmann, MD submitted the following additional substantiation: I support and agree with the above revision.
- Jeff Wong, MD submitted the following additional substantiation: I support the above proposal because R.N.'s have a greater knowledge base making it more likely that they can contribute positively to a patient's care. It also decreases the likelihood of a circulating nurse causing harm to a patient.
- Roberta Harrison submitted the following additional substantiation: A registered nurse that circulates in the operating room has specific training & knowledge on the care of the patient. The registered nurse is an advocate for the patient and upholds the current AORN standards & practices. She has specific knowledge about safety, medications & the special needs of each patient.

- Lois Pate submitted the following additional substantiation: The circulator in the OR setting should be a registered nurse who understands the practice in this specialty area. A knowledge base of clinical nursing underlies clinical competency and reflects a foundational requirement for the development of someone who not only understands what is occurring in the surgical suite, but has the ability to anticipate and foresee potential problems. While I do believe a surgical tech may be valuable, it remains a technical role. This position cannot replace the skill and ability of the registered nurse as the circulator.
- Kristine Gunn submitted the following additional substantiation: As a patient I feel that it's very important to have an RN present for every OR procedure for their specific, extensive training and attention to proper procedure and patient care.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

Assure that a registered nurse qualified by training and functions as the circulating nurse throughout every surgical or invasive procedure ~~in the operating room~~.

Meeting discussion: See modifications made by group. There was considerable discussion regarding the appropriateness of singling out operating rooms.

Proposal 038 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH text changes. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 039 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH proposal to make medical screening exam language consistent with Federal Medicare rules. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 040 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH proposal to have hospitals incorporate clinics and outpatient settings with all policies and procedures. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 041 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH text revision re life safety. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 042 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-405
Recommendation: Proposal would mandate each hospital designate a person or persons responsible for life safety, medical equipment, emergency preparedness, etc. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 042 - Comment 2 **Not Supported**

Submitter: Byron Plan
Section: 246-320-405
Recommendation: DOH recommends not eliminating a reference to medical gas piping requirements. RCW 70.41.030 reads: "…the department shall adopt standards that are at least equal to recognized national standards

pertaining to medical gas piping standards." These standards address construction and maintenance/operation of medical gas systems.

(iv) Medical gas piping meeting requirements ~~in WAC 246-320-99902 (6) and (10);~~

DOH recognizes that the reference to specific sections will no longer exist. However, in order to provide a patient safe environment, the items proposed to be eliminated to remain in some form. Properly functioning nurse call systems, clean interior surfaces/finished and electrical receptacles that are safe and do not place pediatric patients at risk of harm are necessary.

d) Clean interior surfaces and finishes ~~suitable to the function in accordance with WAC 246-320-525(6);~~

e) ~~Electrical with;~~

i) Fully operating patient call systems ~~in accordance with WAC 246-320-525 (Table 525-1); and~~

ii) Tamper resistant receptacles in waiting and other areas and where pediatric patients receive care ~~where noted in Table 525-5 and WAC 246-320-99902(3).~~

(Delete this references (d and e) to WAC 246-320-525 as these codes and standards should only apply when related to design and construction and will be referenced for new construction in the AIA Guidelines.)

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Not Supported

Modified proposal as follows: There were two suggestions to revise text as follows:

Modify to read:

ii) Tamper resistant receptacles ~~in waiting and other areas and where pediatric patients receive care~~ shall be provided per National Electrical Code on specific populations.

Omit the following: ~~(iv) Medical gas piping meeting requirements in WAC 246-320-99902 (6) and (10);~~

Meeting discussion: Participants encouraged the Department to consider referencing and/or adopting the National Electrical Code as the standard for addressing tamper resistant receptacles.

Proposal 043 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Increase in late fee for license renewal. Support

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 044 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: To include review of a non-hospital Ambulatory Surgery Center in fees offered. Unsure

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 044 - Comment 2 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-
Recommendation: Section ~~246-320-990~~
Recommendation: ~~Include review of non-hospital based Ambulatory Surgery Centers in services offered; fees collected by DOH CRS.~~

Substantiation: DOH does not support this proposal. The hospital licensing law (RCW 70.41) under which these rules are authorized to be written and adopted pertain only to hospitals. That law does not include any reference to grant the department authority to regulate non-hospital based ambulatory surgery centers or any other non-hospital based facility.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 045 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-145
Recommendation: DOH proposal incorporate HB 2929 (disclosure of unanticipated outcomes) and develop rules. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 045 - Comment 2 **Tabled Discussion**

Submitter: Washington State Hospital Association
Section: 246-320-145
Recommendation: The required root cause analysis must include consideration of whether human resource factors contributed to the adverse event, including, but not limited to, whether staffing levels, communication amongst the staff, or orientation and training were relevant to the event.

Substantiation: This comment is based on the JCAHO model for root cause analysis of an adverse event. The comment assures every hospital looks at staffing no matter which method of root cause analysis is chosen. The comment is consistent with the outcome-based focus of the hospital licensing rules.

Level of Support: Tabled Discussion – the group agreed this discussion will be deferred to a future public forum.

Modified proposal as follows:

Meeting discussion: This discussion will be tabled / deferred to a future public forum.

Proposal 046 – Comment 1 **Supported as Proposed**

Submitter: Byron Plan
Section: 246-320-
Recommendation: The legislature passed and the governor signed HB 1672 (Safe Patient Handling) this spring. This law affects hospital operation and as such should be added to the rules being considered.

NEW SECTION
Hospitals must establish and implement a safe handling patient committee in accordance with RCW 70.41.XXX.

Hospitals must establish and implement a safe patient handling program in accordance with RCW 70.41.XXX. The program must include:
A safe patient handling policy,
A patient handling hazard assessment,
An annual performance evaluation of the program,
An annual staff training on all safe patient handling policies, procedures, equipment and devices, and
Procedures for hospital staff to follow who refuse to perform or be involved in patient handling or movement.

Substantiation: Incorporate requirements from HB 1672 into the rules.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

Proposal 046 - Comment 2 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: DOH to consider language to implement HB 1672 (safe patient handling, no lift). Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 048 - Comment 1 **Supported with Modification**

Submitter: Mike Kelley, Martha Boes, AHP, Chad Beebe
Section: 246-320-505
Recommendation: Revise Text as follows:

1) Drawings and specifications for new construction, excluding minor alterations, must be prepared by, or under the direction of, an architect registered under chapter 18.08 RCW. The services of a consulting engineer registered under chapter 18.43 RCW must be used for the various branches of the work where appropriate. The services of a registered professional engineer may be used in lieu of the services of an architect if work involves engineering only.
2) A hospital will meet the following requirements:
a) **Pre-submission Conference:** Attend a pre-submission conference for projects with a construction value of $100,000 or more. The pre-submission conference shall be scheduled to occur for the review of construction documents that are 90% complete.
b) **Plan Review Submission timing:** Submit construction documents for proposed new construction to the department for review at the time of submission to the local authorities. approval prior to occupying the new construction. as specified in this subsection, with the exception of administration areas that do not affect fire and life safety, mechanical and electrical for patient care areas. Compliance with these standards and regulations does not relieve the hospital of the need to comply with applicable state and local building and zoning codes.
c) **Construction Documents:** The construction documents must include:
i) A written program containing, at a minimum: (1) Information concerning services to be provided and operational methods to be used; and (2) An Interim Life Safety Measures (ILSM) plan to show how they will ensure the health and safety of occupants during construction and installation of finishes. This includes (3) An Infection Control Risk Assessment (ICRA) indicating taking appropriate infection control measures, keeping the surrounding area free of dust and fumes, and assuring rooms or areas are well-ventilated, unoccupied, and unavailable for use until free of volatile fumes and odors;
ii) Drawings and specifications to include coordinated architectural, mechanical, and electrical work. Each room, area, and item of fixed equipment and major movable equipment must be identified on all drawings to demonstrate that the required facilities for each function are provided; and
iii) Floor plan of the existing building showing the alterations and additions, and indicating: (1) Location of any service or support areas; and (2) Required paths of exit serving the alterations or additions.
d) **Written Responses:** The hospital will respond in writing when the department requests additional or corrected construction documents;
e) **Understanding of Risks:** Notify the department in writing when construction has commenced; provide the department with a written document acknowledging the “understanding of risks” associated with beginning construction before the plan review has been completed and agree to make modifications as required by plan review citations before occupancy. This document shall be signed by the:
i) Architect; and
ii) Hospital CEO or COO; and
iii) Hospital Facilities Director
Proposal # Level of Support Comment #
f) **Addenda and Modifications:** Submit to the department for review any addenda or modifications to the construction documents;
g) **Compliance with approvals:** Assure construction is completed in compliance with the final "department approved" documents. Compliance with these standards and regulations does not relieve the hospital of the need to comply with applicable state and local building and zoning codes. Where differences in interpretations occur, the hospital will follow the most stringent requirement.
h) **Inspections:** The hospital will allow any necessary inspections for the verification of compliance with the construction document, addenda, and / or modifications.
i) **Notification of Construction Complete:** Notify the department in writing when construction is completed and include a copy of the local jurisdiction's approval for occupancy.
3) The hospital will not begin construction use any new or remodeled areas until:
a) The Infection Control Risk Assessment (ICRA) has been approved by the department.
b) The interim Life Safety Plan has been approved by the department.
c) A “Understanding of risk” document has been submitted to the department as required by section 2) e)
d) The construction documents are approved Authorization to begin construction has been granted by the department; and
e) The local jurisdictions have issued a building permit, when applicable. approval to occupy.
4) The Department will:
a) Issue an “Authorization to Begin Construction” when subsections 3) a), b), and c) are approved and a 90% presubmission conference is concluded.

Substantiation:
1. No changes made to this paragraph.
2. Several responsibilities for the hospital have been added and / or arranged in this section to make it clearer.
a. The requirement to have a 90% pre-submission conference has been added for projects over $100,000 in construction value. This value does not include equipment costs. The pre-submission conference does not necessary have to be conducted in Olympia.
b. Timing for submission of the construction documents has been added so that it is congruent with the submission to the local authorities. This gives the department the opportunity to coordinate and eliminate duplicative review by working with local authorities.
c. This section has been clarified and utilizes the same terms used by other regulating entities i.e. ICRA and ILSM
d. No modifications made to this section
e. This section requires facilities to acknowledge that they will comply with the plan review citations, and that they fully understand the potential and costly risks associated with proceeding with construction without a complete plan review.
f. Adds clarification that addenda and modifications such as change orders need to be approved by the Department.
g. Requires facilities to comply with the approved documents, also clarifies that the codes and standards must be met that are enforced by local authorities. (this statement was moved to this section from above.) This also includes a clarification on how joint jurisdictional review is conducted and what to do when there is a difference between the state/federal requirements and the local requirements.
h. A section for inspection has been added. Inspections allow the department to verify compliance several types of minor issues instead of resolving them in plan review and reduces plan review time.
i. No changes were made to this section
3. This section outlines the minimum that is required before a facility can begin construction. This is a list of items that should be able to be resolved during the pre-submission conference. It also ensures that facilities realize that issuance of a permit by the local, doesn't necessarily mean that they are ready to begin construction without authorization from Construction Review and vise versa. Not all projects will require items a) and b), however a simple statement from the facility accompanying their "Understanding of Risk" explaining the project and why these two items are not needed will suffice.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

2) A hospital will meet the following requirements:
a) **Pre-submission Conference:** Attend a pre-submission conference for projects with a construction value ~~$100,000~~ $250,000 or more. The pre-submission conference shall be scheduled to occur for the review of construction documents that are ~~90%~~ 50% complete.
e) **Understanding of Risks:** Notify the department in writing when construction has commenced; provide the department with a written document acknowledging the "understanding of risks" associated with beginning construction before the plan review has been completed and agree to make modifications as required by plan review citations before occupancy. This document shall be signed by the:
i) Architect; and
ii) Hospital CEO~~, or~~ COO or designee; and
iii) Hospital Facilities Director
~~Proposal # Level of Support Comment #~~

Meeting discussion: Geoff Glass stated that he would prefer "substantive" addenda or modifications for (f). Chad Beebe noted that the term substantive is difficult to define, a seemingly small relocation of a wall to accommodate some utilities could reduce an O.R. below the minimum workable space requirements, not discovered until the building is complete costs facilities money and it may be concluded that the O.R is unusable. Mr. Beebe also noted that the additional paperwork submitted would not be a burden to the department, also there will be no requirement for the department to "approve" the changes or addenda before the hospital proceeds and CRS will make it top priority to review changes as they are submitted and report back to facilities any potential compliance issues. The preferred method for this communication is through email.

Proposal 049 - Comment 1 **Commentary**

Submitter: **Julia A Weinberg**
Section: 246-320-505 (2) (a)
Recommendation: Strongly support revised language as originally proposed to ensure that new construction will accommodate patient handling equipment.

Substantiation: The hospital for which I am currently working is constructing a new 220,000 sq. ft. expansion. I have requested the hospital board of directors and Administration to strongly consider installing lift tracks in the ceilings within the Operating Room, and throughout the new facility in patient rooms and other departments where lifting and transfers occur frequently.

This language would help to make this a mandatory required matter of decision making and not just a consideration, based on what they can or will afford to do for staff and patient safety when it comes to lifting devices.
I have been ill-affected with a chronic back injury and leg pain as a result of a back injury I sustained about 10 years ago. Having the needed equipment readily available in the patient rooms rather than parked somewhere down a hall or on another floor or in an inaccessible hallway, and maybe all of the parts are there, and is it working?; would be an investment not only for me, so I do not suffer more trauma, but new staff and others, and especially our patients do not suffer injury either.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 2 **Commentary**

Submitter: Jean Erickson
Section: 246-320-505 (2) (a)
Recommendation: Strongly support revised language as originally proposed to ensure that new construction will accommodate patient handling equipment.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 3 **Commentary**

Submitter: Patricia Di Egidio Tobis
Section: 246-320-505 (2) (a)
Recommendation: Strongly support revised language as originally proposed to ensure that new construction will accommodate patient handling equipment. This is absolutely essential as we [baby boomers] age and require proper equipment to help patients.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 4 **Commentary**

Submitter: Kathleen Gilbertson-Stimpfle
Section: 246-320-505 (2) (a)
Recommendation: Strongly support revised language as originally proposed to ensure that new construction will accommodate patient handling equipment.

Substantiation: I belong to the Employee Safety Committee at Sacred Heart Medical Center, Spokane, WA. I provide direct bedside care as an RN.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 5 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Requires input from direct-care providers re new construction and safe patient handling. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 6 **Commentary**

Submitter: Cathy
Section: 246-320-505 (2) (a)
Recommendation: Strongly support revised language as originally proposed to ensure that new construction will accommodate patient handling equipment.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 7 **Commentary**

Submitter: Rep. Dawn Morrell, RN
Section: 246-320-
Recommendation: I strongly support this comment as submitted and suggest that DOH include it in the rule revision.

Substantiation: This language would help to make safe patient handling something that must be considered where there is new construction at a hospital. This is important due to the high number of back and musculoskeletal injuries that health care workers have due to the manual moving, transferring and repositioning of patients. Safe patient handling equipment has virtually eliminated the need to have manual patient handling and theses technologies should be considered when new construction occurs.

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 049 - Comment 8 **Commentary**

Submitter: Rep. Dawn Morrell, RN
Section: 246-320-505 (2) (a
Recommendation: Strongly support revised language as originally proposed to ensure that new construction will accommodate patient handling equipment

Substantiation: I strongly support this proposal in order to give quality patient care

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 058 - Comment 1 **Supported with Modification**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Maximum number of beds per room shall be two. Unclear if this includes PACUs and NICUs.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Supported with Modification

Modified proposal as follows:

Meeting discussion: DOH – PACU's and NICU's do not have requirements for number of beds.

Proposal 060 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Allows for a waterless cleaner in lieu of a sink for certain areas. Support.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 068 - Comment 1 **Commentary**

Submitter: Nursing Commission
Section: 246-320-
Recommendation: Removes the requirement for Labor rooms to be arranged for observation from a nursing station. Support. For larger units with LDRs and LDRPs this not feasible.

Substantiation: NO SUBSTANTIATION PROVIDED

Level of Support: Commentary

Modified proposal as follows:

Meeting discussion: This comment did not propose a change and therefore is taken as advisory only.

Proposal 073 - Comment 1 **Supported with Modification**

Submitter: Construction Review Program
Section: Guidelines 6.1.1.4
Recommendation: Add new paragraph as follows:

6.1.1.4 Pharmacy
Until final adoption of USP 797 by either federal or other state programs, facilities may request voluntary plan review for conformance to USP 797 with their initial submission to the Department of Health, Construction Review Services. The most current edition at the time of application of USP 797 will be used for the plan review service.

Substantiation: JCAHO has already adopted UPS 797 and is requiring facilities to comply within a published timeframe. Several facilities have recognized the importance of complying with this standard and have requested that their construction documents be reviewed for conformance.
The American Society of Healthcare Engineers has expressed concern over the way USP 797 is written. It is likely that revisions to this document will be made so that it conforms with standard regulatory format, formal adoption of this standard is pre-mature at this time, however facilities that wish to build in the infrastructure should be able to have the option to do so, and ask for Construction Reviews assistance.

Level of Support: Supported with Modification

Modified proposal as follows: Revise text as follows:

6.1.1.4 Pharmacy
Until final adoption of USP 797 by either federal or other state programs, facilities may request ~~voluntary~~ plan review for conformance to USP 797 with their initial submission to the Department of Health, Construction Review Services. The most current edition at the time of application of USP 797 will be used for the plan review service.

Meeting discussion: The group discussed the need for the word "voluntary" on the paragraph. The word "voluntary" made it unclear if facility was the one to determine if it was voluntary, or if the intent was that the department could voluntarily require such a review, or that the review was voluntary and therefore would not require a fee. The word was stricken as result of the discussion. The intent is that the facility may request the review, the department will still charge a plan review fee per Chapter 246-314 WAC, however compliance to USP 797 is voluntary until required by some other provision.

Proposal 077 - Comment 1 **Supported as Proposed**

Submitter: Construction Review Program
Section: 246-320-505
Recommendation: Retain text as written in the Guidelines.

Substantiation: Individual room control is not important as a *minimum requirement*. An individual patient's needs are important, however it should be up to the facility to determine how this is accomplished. Zone temperature control should be adequate as a minimum requirement.

Level of Support: Supported as Proposed

Modified proposal as follows:

Meeting discussion: No additional discussion noted. See substantiation.

ADVISORY COMMENTS

The following comments were received after the June 21, 2006 public meeting and will be taken as advisory only.

I am the Facilities Director at Highline Medical Center and would like to make known my vote for Proposal #042 as presented at the March 21, 2006 public hearing and I am not in favor of comment 2 to proposal #042 as proposed by Byron Plan and the Department of Health. Thank you for the opportunity to voice my opinion to this process.

Dianne Munroe
Director, Facilities
Highline Medical Center

I wish to comment and ask you to entertain our objection to comment # 2, authored by Byron Plan, in reference to revisions of 246-320-405:

The intent of our objection to this comment is that it effectively re-inserts specific language into the rules which are best covered in the Construction Review Process. It is also our understanding that as we move to be more in synch with JCAHO and with the AIA construction guidelines, CRS will be referencing these in reviews. We do not need this type of specific language in the body of the 246 standard. Please allow CRS to provide the much improved consultation and review and guide the work with our hospitals as we work together to make Washington a healthier place.

We would ask that you adopt the original language of the proposal for -042 as submitted. Thank you for your consideration.

C.R.Barnes, MBA
Executive Director Support Services
Administration
Kennewick General Hospital

I would like to let you know that I am in favor or the original proposal # 042 that was supported in principle during the March 21, 2006 public hearing and am not in favor of the Comment 2 to proposal # 042 as proposed by Byron Plan and DOH. Thanks.

Steve Broussard
Director of Support Services

Prosser Memorial Hospital

I am writing in support of Proposal 042 as submitted by Geoffrey W. Glass with support for the original proposal #042. The original proposal 042 was supported in principle during the March 21, 2006 public hearing. Mr. Glass is representing Facility Managers all over the state of Washington in his proposal to remove retroactive facility improvements from the operational section of the WAC 246-320-405. I agree completely with the original proposal 042 and encourage you to take action based upon this proposal.

I am not in favor of the DOH proposal that was submitted at the public hearing.

Thank you.

Larry Baer
Director of Facilities

St. Mary Medical Center
Walla Walla, WA 99362

I would like to add my voice to that of my fellow WSSHE members and give a definite NO vote to comment 2 for proposal #042 and a YES vote to the original language of proposal # 042. Please feel free to contact me if there are any questions. Thank you for your time.
Sincerely,
Stephen M. Mosher
Director of Plant Operations
Valley General Hospital

Regarding proposal #042, I am in favor of the original proposal that was supported in principle during the March 21, 2006 public hearing and NOT in favor of the Comment 2 to proposal#042 as proposed by Mr. Plan and the DOH.

Mike Kelly

Thank you for your able and focused attention at the hearings in Tacoma. I was impressed by the tenor and thoughtfulness of all DOH employees in attendance.

I submit a vote for proposal #2 as submitted. I do not support the comment #2 as proposed in the hearings.

Respectfully

Art

Art Kjos, Principal
CLARK//KJOS **ARCHITECTS, LLC**

My firm specializes in the planning and design of healthcare facilities. I was discussing the results of the public hearing held June 21, 2006 re: changes in construction and licensing requirements for Washington State with one of our clients and was asked to touch base with you regarding comment #042 - an issue that surfaced at that meeting.

I believe that the original intent of the proposal was to remove all construction related issues (ie: existing medical gas piping, air flow, nurse call and tamper outlets) from the operational WAC (246-320-405) and to deal with these issues as construction items during CRS review. Please note that I would like to make it clear that I am in favor of the original proposal presented during the March 21, 2006 public hearing.

In general, I believe that the changes being made to the WAC are productive and will improve patient care in Washington State but I cannot support retroactive construction changes, i.e. Byron's proposal outlined in 'comment 2' at that meeting.

Thank you for your time and attention with this issue.

Yours,

John Wm. Scherer, AIA
Principal

I write to you today to declare my support for the originally offered Proposal 042 as amended below. I am not in favor of the adoption of Proposal 042 - Comment 2, copy also attached below. Thank you for your time in this matter.

Donald Larson
Director Ops. & Maint./Safety Ofcr., BS, CHSP
University of Washington Medical Center

I'm communicating today in support of the original WSSHE proposal #042, as presented during the March 21,2006 public hearing, and specifically not in support of comment 2 to that proposal.

In these days of diminishing reimbursements for services, and ever increasing regulation in the name of safety, opening the door to retroactive code enforcements targeted at health care providers and their facilities is a totally unreasonable position.

Kevin Stolhammer

I favor the original proposal #042 and oppose comment 2 to proposal #042

Thank you,

Brad Jones
Property Management Division Director
C.W.C.M.H.

Proposal # 042 (WAC 246-320-405), as proposed on March 21, 2006, should not be amended to even hint of any retroactive application of any construction code for hospitals. Retroactive code application is almost always 100% unadvised by almost every legislative or judicial body in the United States. If there exists a loop hole to proposal #042 that allows this to happen, then the economic impact to hospitals will be severe. The healthcare industry is booming and has become a consumer choice market. Trying to regulate past construction with any new development could single handedly slow down progress in our state because the fear of retribution and what it might cost would stop further improvements needed to remain afloat in an increasingly competitive market.

Kristyn Clayton, WSSHE
Project Coordinator
Kadlec Medical Center

I'm very in favor of the original proposal #42 that was supported in principle during the March 21,2006 public hearing.

I'm not in favor of the Comment 2 to proposal #42 as proposed by Byron Plan and DOH.

Thank You
Melvin Larsen
Engineer II
Island Hospital

I want to take some time to let you know that I am in favor of the original proposal #042 as was supported in principle at the March 21st public hearing. I am not in favor of the comment 2 proposed by Byron Plan and DOH. The burden of retroactive const. requirements in the future would have too big of an impact on our businesses and we feel the inspection process in place now is more than adequate to deal with the health and safety that is important to all of us

Thank You.

Dan Clark , Director of Facilities.

I would like to support the language that would require a staffing committee, with at least 50% nursing involvment. My reasoning in part follows:

- Hospitals exist primarily to provide nursing care, without nursing care, it is something else.
- The best science and evidence to date shows a direct relationship between nursing staffing and safe patient outcomes (something I am certain the DOH wishes to ensure)
- Hospitals are already required to have committees for many issues- infection control and ethics to name two. Based on this, it seems logical to now *prescribe* the formation of staffing committees since the evidence shows such strong correlation.
- How the hospital forms the committee, the size, the frequency of full committee meetings, etc, is still up to the hospital.
- Addressing this need in patient/staff safety here, in the WAC allows for non-partisan language. If this issue is not addressed here, it will be addressed in the legislature in the near future....because the science is there, the need is identified, and the individuals invested in the issue will make sure it does. Let's get it right in Washington.

Sincerely,
Wendelyn (Wendy) Valentine RN, MSN, CNOR, CWCN

Based on the discussions which began on the hospital licensing rules on June 21st, here are some additoinal comments in reponse to the discussion surrounding proposal #4 on staffing plans.

Thank you for this opportunity to sumbit these additional suggestions. Please let me know if you have any questions.

Anne Tan Piazza
Director of Gov. Affairs & Communications
Washington State Nurses Association

DOH Proposal[1]	**WSNA Proposal**[2]	**WSNA Rationale**[3]
(a) "Staffing plan ~~committee~~" means a document ~~committee~~ established by the hospital that defines a process individual units of the hospital will use to determine the number and type of direct care staff necessary to safely provide patient care. ~~with at least one-half of its members who are registered nurses currently providing direct patient care. If registered nurses are represented by a collective bargaining representative, the registered nurse representatives must be selected by the collective bargaining representative. Participation in the committee must be~~	(a) "Staffing plan ~~committee~~" means a document ~~committee~~ established by the hospital that defines a process individual units of the hospital will use to determine the number and type of direct care staff necessary to safely provide patient care. ~~with at least one-half of its members who are registered nurses currently providing direct patient care. If registered nurses are represented by a collective bargaining representative, the registered nurse representatives must be selected by the collective bargaining representative. Participation in the committee must be~~	The term "direct care staff" is used frequently in the Department's draft but not defined. The Association understands the Department's interest in including personnel in addition to registered nurses who provide care directly to patients. This is the Association's attempt to define that broader term.

[1] This column reflects the changes proposed by the Department to Proposed Change Number 4 to the Department's Hospital Licensure Regulations.
[2] This column reflects WSNA's proposed changes to the Department's language. WSNA's proposed changes are shown with yellow highlighting and underline.
[3] In this column we have provided a brief statement of the rationale for the change proposed.

~~considered a part of the employee's regularly scheduled workweek.~~ ~~(b) "Patient care unit" means any unit of the hospital that provides patient care.~~ ~~(c) "Intensity" means the level of patient needs as determined by a registered nurse providing direct patient care taking into account at least the following factors:~~ ~~(i) Severity and urgency of the patient's admitting condition;~~ ~~(ii)Scheduled procedures;~~ ~~(iii)Patient's ability to meet health care requisites;~~ ~~(iv) Patient's availability of social supports;~~ ~~(v) Age and functional ability of the patient;~~ ~~(vi)Communications skills of the patient; and~~ ~~(vii)Other needs identified by the patient and by the registered nurse.~~ ~~(d) "Skill mix" means the number of registered nurses, licensed practical nurses, and unlicensed assistive personnel providing direct patient care~~.	~~considered a part of the employee's regularly scheduled workweek.~~ ~~(b) "Patient care unit" means any unit of the hospital that provides patient care.~~ ~~(c) "Intensity" means the level of patient needs as determined by a registered nurse providing direct patient care taking into account at least the following factors:~~ ~~(i) Severity and urgency of the patient's admitting condition;~~ ~~(ii)Scheduled procedures;~~ ~~(iii)Patient's ability to meet health care requisites;~~ ~~(iv) Patient's availability of social supports;~~ ~~(v) Age and functional ability of the patient;~~ ~~(vi)Communications skills of the patient; and~~ ~~(vii)Other needs identified by the patient and by the registered nurse.~~ ~~(d) "Skill mix" means the number of registered nurses, licensed practical nurses, and unlicensed assistive personnel providing direct patient care~~. (b) "For the purposes of this section, "direct care staff" means non-managerial staff who spend a majority of their time providing patient care, including but not limited to registered nurses and licensed practical nurses,	
(2) A ~~Each~~ hospital must ~~in the state shall~~ develop and implement a~~s~~ staffing plan ~~for nursing services~~. The plan must be reviewed and updated annually and ~~filed with the department. The written staffing plan~~ must:	(2) A ~~Each~~ hospital must ~~in the state shall~~ develop and implement a~~s~~ staffing plan ~~for nursing services~~. The staffing plan shall reflect the participation of direct care staff and shall include a description of the process by which such participation was solicited and utilized.. The plan must be reviewed and updated annually and ~~filed with the department. The written staffing plan~~ must:	In order for the staffing plan to be meaningful and realistic, it must be developed in collaboration with the nurses and other caregivers who are at the bedside. Thus, a critical component of the development of a staffing plan is the a mechanism for the Hospital to receive and take into account input from direct care providers.
(a) ~~Set~~ Include a ~~the~~ minimum number of direct care staff ~~and skill mix of registered nurses, licensed practical nurses, and unlicensed assistive personnel required~~ in each patient care unit ~~in the hospital~~;	(a) ~~Set~~ Include a ~~the~~ minimum number of direct care staff , including, but not limited to, numbers of registered nurses, licensed practical nurses and unlicensed nursing personnel ~~and skill mix of registered nurses, licensed practical nurses, and unlicensed assistive personnel required~~ in	The Department's draft expands the staffing plan to include staff beyond registered nurses and including other classifications of direct care employees. With a broader

	each patient care unit ~~in the hospital~~;	array of caregivers its is important for the plan to distinguish among them and to be explicit as to the staffing level for each type of direct care staff.
(b) ~~Be based on at least the~~ Evaluate the following criteria ~~on each patient care unit~~: (i) Patient census, ~~including activity such as patient discharges, admissions, and transfers;~~ Patient turnover (discharges, admissions and transfers), Patient acuity; (ii) Level and type of patient care ~~intensity of all patients and nature of the care~~ to be delivered on each shift; (iii) Skill level ~~mix~~, experience, and specialty certification or training of staff assigned to provide ~~those providing the~~ care; (iv) ~~The need for~~ Specialized or intensive equipment; (v) The physical layout and location ~~architecture and geography~~ of the ~~patient care~~ unit; and (vii) The staffing guidelines of national ~~nursing and specialty nursing~~ organizations.	(b) ~~Be based on at least the~~ Take into account the following criteria ~~on each patient care unit~~: (i) Patient census, ~~including activity such as patient discharges, admissions, and transfers;~~ Patient turnover (discharges, admissions and transfers), Patient acuity; (ii) Level and type of patient care ~~intensity of all patients and nature of the care~~ to be delivered on each shift; (iii) Skill level ~~mix~~, experience, and specialty certification or training of staff assigned to provide ~~those providing the~~ care; (iv) ~~The need for~~ Specialized or intensive equipment; (v) The physical layout and location ~~architecture and geography~~ of the ~~patient care~~ unit; and (vii) The staffing guidelines of national ~~nursing and specialty nursing~~ organizations.	The word “evaluate” is a bit unclear as to the responsibility imposed on the hospital. At a minimum, the Association believes that the staffing plan should be developed in light of the criteria that follow and that the hospital be required to demonstrate how the criteria have been taken into account in their staffing plan.
~~(c) Include appropriate limits on the use of agency and traveling nurses~~; (d) Be consistent with the scope~~s~~ of practice for all licensed, certified or registered direct care staff ~~registered nurses and licensed practical nurses and the authorized duties of unlicensed assistive personnel~~; (e) ~~Include adequate staffing to~~ Provide for staff time off, illnesses, meal and break time, and educational, health, and other leaves;	~~(c) Include appropriate limits on the use of agency and traveling nurses~~; (d) Be consistent with the scope~~s~~ of practice for all licensed, certified or registered direct care staff and within the scope of permissible duties of other staff ~~registered nurses and licensed practical nurses and the authorized duties of unlicensed assistive personnel~~; (e) ~~Include adequate staffing to~~ Provide for staff time off, illnesses, meal and break time, and educational, health, and other leaves;	For consistency and clarity, this section should reflect the limitation on the scope of duties for unlicensed staff as well.
~~(f) Include a semiannual process for internal review by the staffing committee that ensures compliance with the staffing plan, provides for the review of incidents and staff concerns, and tracks staffing patterns, number of patients, and their acuity~~	f) Provide a mechanism for at least quarterly evaluation of the plan. This evaluation shall reflect participation by direct care staff and shall include (1) evaluation of the implementation, utilization and effectiveness of the plan ; (2) review of staffing-related adverse patient events; (3) review of staff and patient	Rather than providing a for a committee responsible for reviewing the plan, this proposal leaves it to the hospital to determine the mechanism for evaluation provided that includes participation by direct care staff.

	complaints, if any, regarding staffing; (4) documenting the findings and results of this evaluation.	
~~(3) The staffing plan must not diminish existing standards in law, rules, or the terms of an applicable collective bargaining agreement.~~ (4) Each hospital must ~~shall~~ implement and monitor ~~staff each patient care unit in accordance with it's~~ the staffing plan~~.~~ and make shift-to-shift adjustments ~~in staffing levels required by the plan may be made only if~~ based upon assessing patient needs and safety ~~by a registered nurse providing direct patient care on the patient care unit~~. ~~(5) Each hospital shall post the staffing plan for that patient care unit as required by this section on each patient care unit in the facility.~~	3) Each hospital shall utilize the staffing plan in determining levels of direct care staff assigned in each unit to provide patient care. The hospital shall employ a process for monitoring the implementation of the plan and for making adjustments in staffing based on at least a shift-to-shift assessment of patient needs and the criteria listed in (2)(b) above.	The Association proposes this new language which incorporates the Department's changes and makes clear the hospital will use the plan in making staffing determinations on a unit-by-unit basis.
~~(~~10) Hospitals must ~~shall~~ maintain and make available to each unit identified in the staffing plan ~~post~~ a list of qualified, on-call ~~nursing~~ staff ~~and nursing services~~ that may be called ~~to provide replacement staff~~ in the event of sickness, vacations, vacancies, and other absences ~~of nursing staff and that provides a sufficient number of replacement staff for the hospital on a regular basis~~.	~~(~~10) Hospitals must ~~shall~~ maintain and make available to each unit identified in the staffing plan ~~post~~ a list of qualified, on-call ~~nursing~~ staff ~~and nursing services~~ that may be called ~~to provide replacement staff~~ in the event of sickness, vacations, vacancies, and other absences ~~of nursing staff and that provides a sufficient number of replacement staff for the hospital on a regular basis~~.	No changes.
~~(11) Semiannually, hospitals shall collect and submit to the department information regarding nurse staffing. In addition to the skill mix of registered nurse, licensed practical nurse, unlicensed assistive personnel and contract employees, and the nursing care house per patient per day, such information must also include at least three of the following National Voluntary Consensus Standards for Nursing Sensitive Care established by National Quality Forum:~~ ~~a) Death among surgical inpatients with treatable serious complications (failure to rescue)~~ ~~b) Pressure ulcer prevalence~~ ~~c) Falls prevalence~~ ~~d) Falls with injury~~ ~~e) Restraint prevalence (vest and limb only)~~ ~~f) Urinary catheter associated urinary tract infection for intensive care unit (ICU) patients~~ ~~g) Central line catheter associated~~	~~(11) Semiannually, hospitals shall collect and submit to the department information regarding nurse staffing. In addition to the skill mix of registered nurse, licensed practical nurse, unlicensed assistive personnel and contract employees, and the nursing care house per patient per day, such information must also include at least three of the following National Voluntary Consensus Standards for Nursing Sensitive Care established by National Quality Forum:~~ ~~a) Death among surgical inpatients with treatable serious complications (failure to rescue)~~ ~~b) Pressure ulcer prevalence~~ ~~c) Falls prevalence~~ ~~d) Falls with injury~~ ~~e) Restraint prevalence (vest and limb only)~~ ~~f) Urinary catheter associated urinary tract infection for intensive care unit (ICU) patients~~ ~~g) Central line catheter associated~~	No changes.

~~blood stream infection rate for ICU and high-risk nursery~~ h) ~~(HRN) patients~~ i) ~~Ventilator-associated pneumonia for ICU and HRN patients~~ j) ~~Smoking cessation counseling for acute myocardial infarction~~ k) ~~Smoking cessation counseling for heart failure~~ l) ~~Smoking cessation counseling for pneumonia~~ m) ~~Practice Environment Scale—Nursing Work Index (composite and five subscales)~~ n) ~~Voluntary turnover~~	~~blood stream infection rate for ICU and high-risk nursery~~ h) ~~(HRN) patients~~ i) ~~Ventilator-associated pneumonia for ICU and HRN patients~~ j) ~~Smoking cessation counseling for acute myocardial infarction~~ k) ~~Smoking cessation counseling for heart failure~~ l) ~~Smoking cessation counseling for pneumonia~~ m) ~~Practice Environment Scale—Nursing Work Index (composite and five subscales)~~ n) ~~Voluntary turnover~~	
~~(12) The department shall investigate complaints of violations of this section.~~ ~~(13) The department shall maintain for public inspection records of any civil penalties, administrative actions, or license suspensions or revocations imposed on hospitals under this section.~~ ~~(14) The department shall conduct an annual random audit of not less than ten percent of all hospitals in this state solely to verify compliance with the requirements of this section. Surveys made by private accrediting organizations may not be used in lieu of the audit required under this subsection. The department shall compile and maintain for public inspection an annual report of the audit conducted under this subsection.~~	~~(12) The department shall investigate complaints of violations of this section.~~ ~~(13) The department shall maintain for public inspection records of any civil penalties, administrative actions, or license suspensions or revocations imposed on hospitals under this section.~~ ~~(14) The department shall conduct an annual random audit of not less than ten percent of all hospitals in this state solely to verify compliance with the requirements of this section. Surveys made by private accrediting organizations may not be used in lieu of the audit required under this subsection. The department shall compile and maintain for public inspection an annual report of the audit conducted under this subsection.~~	No Changes.

I wanted to thank you again for taking the time to walk through the WA rulemaking process with me - It was very helpful and certainly provides comfort in terms of whether we are participating in the right things at the right time.

It was brought to my attention that during the public meeting on June 21st, a question was raised regarding the definition of a circulator and whether other healthcare professionals could serve in the circulating role. At the hearing, some of the stakeholders (AORN members) provided reference to originally submitted materials including definitions of RN Circulator from other state laws and AORN guidance documents. I would like to provide additional information on the definition of the role of the circulator as derived from the Conditions of Participation rules and interpretative guidelines for hospitals in the Center for Medicare and Medicaid Services (CMS). Specifically, 42 CFR 482.51 and the corresponding guidelines state that:

§482.51(a)(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

Interpretive Guidelines §482.51(a)(3)

The circulating nurse must be an RN. An LPN or surgical technologist may assist an RN in carrying out circulatory duties (in accordance with applicable State laws and medical-staff approved hospital policy) but the LPN or surgical technologist must be under the supervision of the circulating RN who is in the operating suite and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies. The supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical technologist. The hospital, in accordance with State law and acceptable standards of practice, must establish the qualifications required for RNs who perform circulating duties and LPNs and surgical technologists who assist with circulating duties.

Additionally, there are a number of medical studies that have demonstrated that the quality of patient care is directly related to increased registered nursing staff. I mention this because while there are no specific studies to demonstrate that "bad things will happen" in the operating room if there is not a registered nurse circulator present, patient safety and quality are most effectively ensured by having qualified registered nursing staff available for patients. More pointedly, no operating room manager would ever remove the RN circulator from a procedure to "see if something bad happened" and thus, the empirical evidence on RN circulators specifically is limited. I would like to bring the following studies to your attention to further demonstrate the important patient safety role that RNs perform in the hospital setting:

"Nurse-Staffing Levels and the Quality of Care in Hospitals" Jack Needleman, Peter Buerhaus, et. al. New England Journal of Medicine (May 2002) - "A higher proportion of hours of nursing care provided by RNs and a greater number of hours of care by RNs per day are associated with better care for hospitalized patients."

"Nurse Staffing Levels and Adverse Events Following Surgery in US Hospitals" Christine Kovner and Peter Gergen. Journal of Nursing Scholarship (4th Q 1998) – "The results of this study show a clear relationship between levels of nurse staffing and avoidable adverse events."

"While You Were Sleeping" Carrie Farella, RN, MA. Nursing Spectrum (October 24, 2005) - Good overview of role of Circulator. http://community.nursingspectrum.com/MagazineArticles/article.cfm?AID=18009

I hope this information is helpful in clarifying any issues regarding the intent of our proposal. Please feel free to contact me with any additional questions.

Thank you.
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